FORM PTO-1390 (REV. 11-2000) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY 'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
09/936741

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/IB00/00408	14 March 2000	15 March 1999

TITLE OF INVENTION
SAFETY TROCAR ASSEMBLY

APPLICANT(S) FOR DO/EO/US
Popov, Sergey

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Aplication under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English lanugage translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:

U.S. APPLICATION NO (If known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
09/936741		

21. ☒ The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):	CALCULATIONS PTO USE ONLY
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO $1000.00	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO $860.00	
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO $710.00	
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) $690.00	
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) $100.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 690.00
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	95 -20 =	75	x **$18.00**	$ 1,350.00
Independent claims	9 -3 =	6	x **$80.00**	$ 480.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$270.00**	$ 270.00
TOTAL OF ABOVE CALCULATIONS =				$ 2,790.00
☒ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.			+	$ 1,395.00
SUBTOTAL =				$ 1,395.00
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$
TOTAL NATIONAL FEE =				$ 1,395.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$
TOTAL FEES ENCLOSED =				$ 1,395.00
			Amount to be refunded:	$
			charged:	$

a. ☒ A check in the amount of $ 1,395.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☐ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. _____. A duplicate copy of this sheet is enclosed.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

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September 13, 2001

OUR FILE NO. 2015.00003

VIA EXPRESS MAIL NO. EL632159333us

Assistant Commissioner of Patents and Trademarks
Washington, D.C. 20231

Re: § 35 U.S.C. 371 Filing of International Application in the United States - National Stage
Applicant: Sergey Popov
Title: Safety Trocar Assembly

Dear Sir:

We enclose the following in furtherance of the referenced matter:

1. Transmittal Letter to the United States Designated/Elected Office Concerning a Filing Under 35 U.S.C. 371;

2. Declaration for Utility or Design Patent Application;

3. Total filing fees of $1,395.00 in a check made payable to the Commissioner of Patent and Trademarks.

4. Certificate of Mailing.

Please stamp and mail the enclosed self-addressed postcard.

Thank you for your assistance.

Respectfully submitted,

Stuart M. Goldstein
Registration No. 28817
Attorney for Applicants

SMG/dml
Enclosures

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SAFETY TROCAR ASSEMBLY

Field of the Invention

The present invention relates to medical equipment, in particular to trocar and similar devices used in surgical procedures and intended for their improvement.

Background of the Prior Art

Trocars are used in medicine for making openings in body cavity walls used further as ports for instrument insertion to body cavity and diagnosis and treatment. When trocar is inserted to body cavity, there is a real danger of interior organ injury by piercing-cutting means entering the body cavity and located at the trocar distal end.

To prevent such a complication, the trocars are equipped with various protectors of piercing-cutting means. However, all known solutions do not eliminate totally the acuity of the problem of accidental puncture wounds of internal organs upon trocar performance.

The safety trocar penetrating instrument is known from the US patent No. 5591190, comprising port unit and trocar unit with obturator on whose distal end there is a piercing-cutting means. The device is equipped with protector for piercing-cutting means made as a tubular shield situated between obturator and tubular cannula of port unit and movable relative to obturator within the range from the extended position when it encloses piercing-cutting means and prevents it from any contact, to the retracted one, when piercing-cutting means is open and can opening in the body cavity wall. Such a protector advances to the extended position when the force applied to its distal edge on the side of body cavity wall is removed, which occurs after complete exit of the exposed piercing- cutting means to body cavity, i.e. after internal organs could have already been injured.

Another trocar and cannula assembly are known from the USA patent No. 5246425, which are equipped with tip protector comprising a plurality of projections which, by the authors' idea should be actuated into an extended position before the piercing apex has been fully inserted to body cavity. However, design predetermines injury of body cavity wall, increased resistance to the device advance, the device advance in jerks, high probability of protector jamming, i.e.

protector does not advance to the extended position upon tip exit into body cavity, and as a consequence, internal organs are injured. drawbacks are the result of the fact that several piercing members are present, that is the tip and the protectors themselves. When these members pass through fibrous anatomical structures: aponeuroses, fascias, muscles, the structure fibers enter either the projections, or between the projections and tip; therefore, further device advance is possible solely by rupturing these fibers which, in its turn, results in increased tissue injury and in the device hindered advance.

The tissue fibers incorporated between projections and tip can jam protector in the retracted position. In this case the jeopardy of internal body injury is even higher than by the performance of a trocar non-equipped with protector, since a surgeon, being sure of the device safety, operates with less caution.

In addition to the protection of patient's organs, the protector is intended for guarding medical personnel from accidental puncture injuries. For this aim the protector is equipped with locking mechanisms which fix it in the extended position. Such locking mechanism is described in the USA Patent No. 5246425. locking means ensures protector fixing in the extended position for any trocar unit position relative to port unit, including the completely assembled one. There are the means for the protector manual de-blocking which preclude the lock mechanism automatic operation. With such a design it is upon the surgeon to decide when lock mechanism should be activated.

Hence, if the surgeon forgets to do it, trocar unit is removed of port unit with inactivated lock mechanism and it is dangerous because medical personnel, being sure of its complete safety, handles the trocar more carelessly. If, by trocar unit setting into port unit, the locking mechanism is inactivated, the port unit sealing means shift it to the retracted position by interacting with protector. Thus, piercing-cutting members pass unprotected through the sealing means area, and can bring to the trocar unit jamming in port unit, or damage sealing means, which results in violation of its de-sealing properties.

Hence, lack of automatically supported link between the device readiness to tissue piercing and locking mechanism condition distract the surgeon to the locking mechanism control, which is inconvenient and unreliable.

A trocar with shield is known from the US patent No. 5797943. The geometry of the

described in the patent shield should, by the authors' opinion, ensure successive protection of various zones in piercing-cutting means practically simultaneously with their penetration to the body cavity.

However, shield members have such sizes, shape, arrangement and contact zone with body cavity wall that they generate considerable resistance between the shield and the body cavity wall tissues, and it holds the shield in totally retracted position, up to the shield complete removal beyond the bounds of body cavity wall, which means that no successive protection of piercing-cutting members takes place as they enter the body cavity.

Similar demerit is found in USA patents No. 5690663, 5709671. A trocar, having improved tip configuration is known from the US patent No. 5709671, where distal edge of tubular cannula is made sloping, to facilitate the device passing through body cavity wall. In fact, the surgeon has less difficulties in trocar passing through tissues since sloping edge of cannula operates as a wedge giving the benefit of force, which facilitates tissue rupture by trocar passing. But tissue injury during the trocar performance remains considerable.

All above described devices lack the means for sealing spacing between cannula and body cavity wall; they also do not have means for hemostasis out of the orifice edges into body cavity wall. These devices do not have reliable means precluding displacement and complete port drop out of body cavity wall.

The US No. 5556411 is known comprising cannula-retaining means made as a movable along the cannula member with sticky surface flanges, which sticks to a patient's skin and ensures cannula fixation.

However, this fixation is insufficiently reliable and does not ensure body cavity sealing.

Summary of the Invention

To facilitate an appreciation of the significance of various features of the present invention, reference is made herein to a range of "objectives". It should be clearly understood, however, that these objectives are not intended as a definitive statement that any particular embodiment described herein satisfies all of these objectives.

The invention objective is decrease of internal organ injury risk upon trocar performance.

Another invention objective is increased reliability of protector operation by preventing

jamming and engagement of body cavity wall tissues between the members of trocar distal edge.

Another invention objective is decreased tissue injury of body cavity wall.

Another invention objective is facilitated trocar passing through body cavity wall.

Another invention objective is decreased material consumption for the device, design simplification and device low-cost manufacturing.

Another invention objective is trocar performance easiness.

Another invention objective is increased safety of medical personnel by trocar operation.

Another invention objective is independent of each other operation start and finish of cutting members dependable on tissue local biomechanical properties.

Another invention objective is accurate adaptation of orifice sizes in body cavity wall to the cannula diameter.

Another invention objective is improved body cavity sealing and precluded gas discharge through the spacing between cannula and orifice edges in body cavity wall.

Another invention objective is ensured hemostasis on the edges of trocar-generated orifice.

Another invention objective is improved fixation of portal unit in the orifice in body cavity wall.

Accordingly, certain preferred embodiments of the present invention provide a trocar assembly including a low-profile retractable shield deployed immediately adjacent to a cutting element with a cross-sectional area which is small relative to the total cross-section of the assembly. In preferred examples, the total cross-sectional area protected by the shield element is less than about 0.4, and most preferably less than about 0.2, of the total cross-sectional area of the assembly. As a result, the shield extends itself as soon as the cutting element clears the tissue wall, prior to penetration of the remainder of the end portion of the assembly. Optionally, such a shield may used in combination with a conventional, large-area shield to provide two-stage protection.

In fuller structural terms, there is provided a safety trocar assembly comprising:

- portal unit with elongated, tubular cannula having an open distal end;
- trocar unit having elongated obturator adapted to be removably inserted through cannula and having a penetrating end exposed through open distal end of cannula and comprising a

penetrating apex mechanical cutting means for making orifice in body cavity wall, and a sloping side wall;

- a protector means situated on obturator and comprising penetrating apex shield adapted to actuate between a retracted and an extended position, when shield surrounds penetrating apex and sloping side wall surrounds shield from the outside;

- distal edge of shield forms a hedge precluding the introduction and engagement of tissue fibers of body cavity wall both between shield and penetrating apex, and between shield segments;

- bias means for biasing shield toward extended position and for permitting shield move to retracted position in response to a proximally directed force applied to shield distal edge, bias means, returning shield to extended position when the force applied to shield distal edge is removed, which occurs when penetrating apex and shield distal edge have entered a patient's body cavity, however, before penetrating end has been fully inserted.

Penetrating apex shield destined only for the protection of penetrating end distal section ensures the penetrating apex protection by its minimal penetration into body cavity which dramatically decreases the possibility of inner organ injury. The embodiment of penetrating apex shield as a penetrating-apex-surrounding hedge facilitates trocar assembly passing through body cavity wall due to the complete preclusion of tissue introduction between the shield members as well as between shield and penetrating apex members, which also decreases tissue injury.

A device, wherein bias means has means made as spring mounted between shield and parts of trocar unit and spring is situated in obturator, preferentially in its distal part.

These embodiments of bias means differ in their simplicity and performance reliability.

A device, wherein shield is tubular.

A device, wherein shield is made as coiled springy rod.

A device, wherein shield is made integral with spring.

Penetrating apex shield in these embodiments totally surrounds the penetrating apex, thus ensuring reliable performance, and their manufacturing is low-cost.

In device, wherein penetrating apex is made as a separate part mounted into obturator, and in this embodiment penetrating apex possesses improved penetrating properties.

In device, wherein penetrating apex is made integral with at least distal part of obturator, it is maximally simple and low-priced in manufacturing.

In device, which has longitudinal central axis and obturator and tubular cannula are situated coaxially with it and wherein:

- the displacement vector of protector means between its extended and retracted position is in the plane parallel to longitudinal axis of trocar assembly;
- cutting means comprises at least one cutting edge situated in the plane parallel to central longitudinal axis of the device so that this plane is the cutting plane of cutting edge;
- protector means has a shield for protecting cutting edge;
- shield has shield outer surface, and as such serves that section of shield surface which in the assembled position of trocar assembly and when shield is in extended position is located distally of open distal end of tubular cannula and protrudes beyond the bounds of members of trocar assembly immovable relative to tubular cannula;
- shield has shield height, and as such serves the distance between cutting plane and shield enter surface;
- shield has shield width, and as such serves the distance between device longitudinal axis and shield outer surface;
- shield has shield local comparative height, and as such serves the ratio of local maximal height of shield to local maximal width of shield measured in their common plane perpendicular to device longitudinal axis;
- shield has proximal protected position, and as such serves the extreme proximal position of shield when there is the complete protection of cutting edge;
- there is a screen area of shield, and as such serves the section of shield which, when shield is located in proximal protected position, is situated between two planes perpendicular to device longitudinal axis so that one of planes intersects the proximal end of cutting edge, whereas the other plane intersects distal end of cutting edge, and the plane equidistant from both perpendicular planes divides screen area into proximal and distal screen zone;

wherein shield has shield zones located bilaterally of cutting plane;

- there is full local comparative height of shield, and as such serves the ratio of total local maximal height of shield and local maximal width, so that total local maximal height of shield

is the distance between outer surfaces of shield zones measured along the line perpendicular to cutting plane;

wherein there is a one-sided low profile shield situated laterally of cutting plane, and shield local comparative height along the proximal screen area is below 0.8;

wherein there is a two-sided low profile shield, and shield full comparative height along the proximal screen area is below 1.4.

The protectors in these embodiments are low profile protectors and have upgraded protection properties. Owing to small area of tissue operated surface such protectors can operate with minimal penetrating means penetration to body cavity.

Device, wherein cutting means comprises penetrating apex cutting means situated inside of penetrating apex shield.

Device, wherein penetrating apex cutting means are situated uniplanarly, whereas penetrating apex has elongated transversal cross-section with largest axis lying uniplanarly with penetrating apex cutting means.

Device, wherein penetrating apex cutting means and outer cutting means are made integral on the plate-shaped base, and penetrating apex shield is made as two-sided low profile shield, and has longitudinal slot, plate base passes through.

The penetrating apex embodiment in plate shape permits to use low profile protector which surrounds penetrating apex.

Device, wherein cutting means has outer cutting means situated outside of penetrating apex shield.

Device, wherein there is at least one outer shield for outer cutting means adapted to actuate between outer shield retracted - unprotected - position and outer shield extended -protected - position, and outer bias means for biasing outer shield toward extended position, permitting shield move to retracted position in response to a proximally directed force applied to body tissue operated surface of outer shield, bias means returning outer shield to outer shield extended position when the force applied to outer shield is removed so that penetrating apex shield and outer shield are movable independently of one another and can be in at least three extreme mutual positions: their simultaneous location in extended and outer shield extended position, respectively;

location of penetrating apex shield in extended position, and outer shield in outer shield retracted position; location of both in retracted and outer shield retracted position, respectively.

Device, wherein outer cutting means have at least one outer cutting member made as a knife mounted on penetrating end between penetrating apex shield and outer shield so that the knife cutting edge protrudes above the surface of sloping wall.

Device, wherein there are two outer cutting members.

Device, wherein there are three outer cutting members.

Device, wherein outer shield surrounds penetrating apex, penetrating apex shield, and outer cutting means.

Device, wherein outer shield is made tubular, and outer biasing means is made as a compression spring.

When cutting means are situated outside of penetrating apex shield there is an outer shield for protection of outer cutting means. Making outer shield tubular is a simple and reliable solution.

Device, wherein outer shield is made as two-sided low profile shield, and comprises two rigidly interconnected plate-shaped shield members mounted bilaterally of outer cutting means.

Outer shield made as low profile protector has upgraded protection properties.

A safety trocar assembly comprising:

- portal unit having elongated obturator with penetrating distal end;
- longitudinal axis of trocar assembly;
- penetrating means for orifice formation in body cavity wall, having at least two penetrating zones: first penetrating zone and second penetrating zone;
- a protector means, having protector member for each of penetrating zones and
- adapted to actuate between a retracted and an extended position, when each protector member has body tissue operated surface which is the section of protector member surface which contacts with body cavity wall tissue and while interacting with body tissue results in displacement of protector member opposite of extended position toward retracted position so that displacement vectors of protector members between their retracted and extended positions are in the planes parallel to longitudinal axis;

- bias means for each of protector members for biasing protector members toward extended position and for permitting protector members move to retracted position in response to a force applied to tissue operated surface, bias means, returning protector members to extended position when the force applied to tissue operated surface is removed so that protector members move independently of one another between their extended and retracted positions.

Presence of independent protector members for each penetrating zone gives trocar assembly improved protection properties.

In this embodiment each protector member guards corresponding penetrating zone upon its minimal protrusion to the body cavity; it also ensures that only that penetrating zone at which level penetrating end is exposed to the increased resistance of body cavity wall tissue, will operate.

Device, wherein penetrating means at the level of at least one penetrating zone is made as cutting member with cutting edge so that cutting edge is situated in the plane parallel to longitudinal axis, and this plane is the cutting plane for cutting edge.

Device, wherein bias means is made as resilient members.

This is an example of a simple and operation-reliable embodiment of penetrating means and bias means.

Device, wherein protector members are made as separate shields.

Device, wherein protector members are made as a common shield for at least two penetrating zones, a penetrating means made as cutting members with common cutting edge so that each of cutting members is protected by corresponding regions of common shield so that each of common shield regions is by its own bias means.

Device, wherein common shield and bias means are made as a single resilient part having a slat which in extended position is basically situated parallel to cutting edge, and resilient elements, each of them being connected to slat by one its end, whereas the other one is connected with the members of penetrating end immovable relative to cutting edge.

Device, wherein common shield in extended position extends beyond the bounds of cutting edge no more than 2 mm in the direction parallel to cutting plane of cutting edge.

Such common shield is actually a floating shield where the displacement direction of protector members optimally corresponds to the direction of tissue impact on tissue operated edge which ensures adequate shield response to the changes in tissue biomechanical characteristics varying from layer to layer.

Device, wherein there is at least one penetrating zone level limited by two planes perpendicular to longitudinal axis, one of them intersecting the extreme distal point of penetrating zone, whereas another one intersects the extreme proximal point of penetrating zone.

Device, wherein there are at least two penetrating zone levels, one being distal and another one, proximal.

Device, wherein a section of penetrating means at the level of penetrating zone and corresponding to it protector member and bias means are a penetration unit so that distal and proximal penetration units are made so that the penetration into body tissue at the level of proximal penetration unit occurs under higher tissue tension than the penetration of tissue at the level of distal penetration unit.

Device, wherein rigidity of proximal bias means of proximal protector unit is higher than the rigidity of distal bias means of distal protector unit.

A safety trocar assembly comprising:

- trocar unit with penetrating means having at least two penetrating zones - distal and proximal - so that penetration of body tissue at the level of proximal penetration zone occurs under higher tissue tension than penetration of tissue at the level of distal penetration zone.

Device, wherein penetrating means at the level of distal and proximal zones are made as cutting members so that distal cutting member is made sharper than proximal cutting member.

Device, wherein there is a protector member for each of penetrating zones so that the displacement of proximal protector member from the extended to the retracted position demands greater effort that the displacement of distal protector member.

Tissue cutting at the level of proximal penetrating zone by its higher tension than at the level of distal penetrating zone precludes formation of extremely large orifice in body cavity wall which improves port unit stability in the orifice, promotes hemostasis due to a good

pressure of orifice edges to the cannula, precludes gas discharge out of body cavity; in post-operation it fastens tissue healing at the orifice level.

Device, wherein there is more than one common shield, and they are situated around longitudinal axis at regular intervals from each other.

Device, wherein distal penetrating unit has cutting member, protector member is made plate-shaped and situated parallel to cutting member, and bias means is made as a flat compression spring.

Device, wherein there is a blunt penetrating apex, and first and second penetrating zones are situated proximally of blunt penetrating apex.

Device, wherein there are two cutting members, whereas protector members are made as plates situated parallel to the corresponding cutting members, and bias means are made as compression springs and blunt penetrating apex is in line with longitudinal axis.

Safety trocar assembly for making orifice in body cavity wall and for portal unit mounting in orifice, comprising:

- central longitudinal axis;
- elongated obturator with distal penetrating end, having blunt apex and cutting means situated proximally of blunt apex.

Presence of blunt apex actually totally precludes inner organ injury by the penetrating apex distal end, i.e. the most commonly occurring complication type by trocar operation.

Device, wherein blunt apex has:

- a base constituted by the section of blunt apex situated at distal point level of cutting means;
- a blunt apex distal point formed by the extreme distal point on the surface of blunt apex;
- blunt apex central axis constituted by the axis parallel to central longitudinal axis and intersecting blunt apex distal point;
- a diameter of blunt apex base constituted by the diameter of a circumference made at the level of base blunt apex and circumscribing the most protruding points on surface of base blunt apex so that the center of circumference is located on central axis blunt apex, and circumference is in the plane perpendicular to central axis blunt apex.

Device, wherein obturator has a diameter constituted by the diameter of the largest circumference with the centers on central longitudinal axis made in the planes perpendicular to central longitudinal axis, and circumscribing the most protruding points on the surface of obturator at the distal half section of obturator so that diameter of base blunt apex constitutes less than 75% of obturator diameter.

Device, wherein diameter of base blunt apex preferably constitutes less than 30% of obturator diameter.

Device, wherein end of blunt apex is round.

Device, wherein the diameter of blunt apex end is less than diameter of base blunt apex.

Said proportions and sizes give trocar upgraded penetrating properties without decrease in safety.

Trocar assembly comprising:

- longitudinal central axis;

- portal unit with elongated tubular cannula, having an open distal end having at least one sloping edge situated in the plane intersecting longitudinal central axis at an acute angle;

- trocar unit having elongated obturator adapted to be removably inserted through cannula and having a cutting means for making orifice in body cavity wall, and exposed through open distal end of cannula;

- cutting means has at least one cutting edge so that proximal end of cutting edge is located proximally of distal point of sloping edge of tubular cannula.

This device embodiment facilitates its passing through tissues, owing to the formation of orifice conforming to the cannula sizes.

Device, wherein there is a cutting plane of cutting edge constituted by the plane intersecting cutting edge and longitudinal central axis.

Device, wherein cutting plane is the symmetry plane of sloping edge.

Device, wherein there are more than one cutting edge having differing cutting planes.

Device, wherein the number of sloping edges corresponds to the number of cutting planes.

Trocar assembly comprising:

- portal unit with elongated tubular cannula and portal unit mounting means for mounting

portal unit in orifice of body cavity wall which has inner mounting means made as inflated cuff mounted on tubular cannula, and there is connector means for cuff connection to the external gas supply.

The inflated cuff is a simple, low-cost and reliable means for the solution of the problem of port unit extreme mobility in body cavity wall.

Device, wherein there is an outer mounting means comprising restraining member movable along tubular cannula, and resistance means precluding spontaneous proximal displacement of restraining member.

Device, wherein restraining member has a flange and an orifice tubular cannula passes through, and resisting means is made as engagement means and has restraining member engagement protrusions situated on inner of orifice, and tubular cannula engagement protrusions situated on outer surface of tubular cannula.

Device, wherein connection means comprises connector with rebound valve and a passage connecting connector and cuff and passing through the wall of tubular cannula.

Device, wherein there is outer sealing means to maintain insufflation of the body cavity precluding gas leakage out of body cavity into the atmosphere through the spacing between portal unit and walls of orifice in body cavity wall, and outer sealing means has seal member, and inflated cuff serves as such.

Device, wherein there is cuff traction means ensuring retaining of inflated cuff against inner surface of body cavity wall in its inflated state.

Device, wherein outer mounting means serve as cuff traction means.

The above mentioned embodiments provide the device both with improved stability within the orifice in body cavity wall and with additional sealing and hemostatic properties.

A safety trocar assembly comprising:

- portal unit with elongated, tubular cannula having an open distal end;
- portal unit has a portal housing located on the proximal end of tubular cannula;
- trocar unit having elongated obturator adapted to be removably inserted through cannula and having a penetrating end exposed through open distal end of cannula, and a cutting means for making orifice in body cavity wall, situated on penetrating end;
- a protector means situated on obturator and adapted to actuate between a retracted and an

extended protected position;

- bias means for biasing protector means toward extended position and for permitting protector means move to retracted position in response to a proximally directed force applied to protector means, returning shield to extended position when the force applied to protector means is removed;

- inner seals located in portal housing and aimed to maintain insufflation of the body cavity;

- locking means which being in lock position locks protector means into protected position, and being in an unlock position unlocks protector means so that locking means unlocks protector means when cutting means is located distally of seals.

The specified principle of lock means operation provides total safety from trocar accidental pricks, and completely precludes potential damage of seals by penetrating means.

Device, wherein locking means has obturator-situated controlling member, partially protruding laterally of obturator and adapted for the interaction with inner surface of tubular cannula for moving abutting member, which is spring-loaded to obturator and has abutting surface for rigid abutment of protector means members, when locking means is in lock position.

Device, wherein cutting means is made as knives, protector means is made as a tubular member, and bias means is made as a spring.

Device, wherein each of independent shields has independent locking means.

Device, wherein penetrating apex shield and outer shield have independent locking means.

Device, wherein there is locking means for one of shields, which in protected position ensures protection of penetrating apex and of all cutting means.

Device, wherein there is locking means to outer shield.

Specified lock means embodiments differ favorably by the design simplicity, performance reliability, and are applicable for various protectors.

Safety trocar assembly comprising trocar unit, having:

- elongated obturator;

- penetrating means situated on distal end of obturator and having at least one penetrating zone;

- a protector means situated on obturator and comprising shield for penetrating zone and

adapted to actuate between a retracted and an extended position;

- bias means for biasing shield toward extended position, and for permitting shield move to retracted position;

- longitudinal central axis of obturator;

- displacement vector of shield between their extended and retracted positions is in the plane parallel to longitudinal axis;

- shield is made as one-sided low profile shield, and situated on one side of cutting plane of penetrating zone, and along the proximal screen area has the shield local comparative height less than 0.8.

A safety trocar assembly comprising:

- longitudinal central axis;

- portal unit with elongated, tubular cannula having an open distal end;

- trocar unit having elongated obturator adapted to be removably inserted through cannula and having a penetrating end exposed through cannula open distal end;

- penetrating means situated on penetrating end;

- a protector means for penetrating means having at least one shield situated on obturator and adapted to actuate between a retracted and an extended position when shield protects penetrating means;

- shield open part, this being the part of shield which when protector means is in retracted position, is situated distally of the plane perpendicular to longitudinal central axis and intersecting the proximal point of the section of outer surface of shield protruding beyond the bounds of the members of trocar assembly immovable with regard to penetrating means and located distally of cannula open distal end;

- common projection of outer surfaces of the members of trocar assembly situated distally of cannula open distal end onto the plane perpendicular to longitudinal central axis, having the center in the intersect point of plane and longitudinal central axis;

- projection width of shield and as such serves the distance between common projection center and its most remote point on shield projection outline;

- relative projection area of shield outer outline which is the ratio of projection area of shield outer outline to the area of the circle with radius equal to projection width

of shield so that relative projection area of shield outer outline is always less than 0.4.

Device, wherein relative projection area of shield outer outline is less than 0.2.

The major property of low-profile protectors is absence of delay in operation. Such protectors have small area of tissue operated surface situated in direct vicinity of the cutting plane, and therefore, by tissue cutting are displaced to the extended position without any significant resistance.

Device, wherein there is a portal unit with elongated tubular cannula, having an open distal end through which penetrating means and shield are exposed so that shield has shield open part and as such serves the section of shield which by shield location in retracted position is situated between two planes perpendicular to longitudinal central axis so that one of them intersects the distal point of shield, and the other plane intersects the proximal point of the section of inner surface of shield protruding beyond the bounds of the members of trocar assembly immovable with regard to penetrating means and located distally of open distal end of tubular cannula.

Device, wherein shield open part situated proximally of screen area has the shield local comparative height less than 0.8.

Device, wherein inner diameter of tubular cannula at the level of open distal end is within 10 mm to 12.5 mm range so that maximal height of shield along the entire shield open part is less than 3.5 mm.

Device, wherein inner diameter of tubular cannula at the level of open distal end is within 5 mm to 6.5 mm range so that maximal height of shield along the entire shield open part is less than 2 mm.

Preferable sizes and proportions of low profile protectors are given.

Device, wherein penetrating zone has cutting edge situated in the plane parallel to longitudinal central axis, and cutting edge has inner end point and outer end point so that inner end point is situated closer to longitudinal central axis than outer end point.

Device, wherein shield is direct shield, and by displacement from extended position to retracted one, it gradually exposes cutting edge from inner end point to outer end point.

Device, wherein shield is delineating shield in which tissue operated edge is made approximately congruent to cutting edge and exposes cutting edge approximately

concurrently along the entire length.

Device, wherein penetrating means is made as a knife, where cutting edge is made in the same plane with longitudinal central axis, shield is made plate-shaped, and bias means is made as a flat compression means.

Device, wherein shield is inverted shield and by its displacement from extended to retracted position it gradually exposes cutting edge from outer end point to inner end point.

Device, wherein there is a blunt apex, two cutting edges situated on the common base set in a longitudinal groove of distal end of obturator so that cutting edges are situated from two opposite sides of obturator distal end at an acute angle to longitudinal central axis, whereas shield is made plate-shaped and has two tissue operated edges, one for each cutting edge so that tissue operated edges are made tilted with regard to longitudinal axis so that their tilt angle is less than tilt angle of cutting edges, and bias means is made as a compression spring, and there is a lock means for blocking shield in extended position.

Device, wherein there is more than one penetrating zone and there is an inverted multishield having protector members for each penetrating zone so that protector members are on a common base and upon displacement from extended to retracted position expose penetrating zones from proximal to distal one.

Device, wherein cutting edge is situated at an acute angle to longitudinal central axis, and tissue operated edge of shield is made stepwise, and bias means is made as a compression spring,

The examples of low profile protector embodiments are given.

Brief Description of the Drawings

Various embodiments of the safety trocar assembly of the subject application will be described below with reference to the following drawings wherein:

Fig. 1 is a perspective view of trocar assembly with tubular penetrating apex shield.

Fig. 2 is a longitudinal section of trocar assembly of the Fig. 1.

Fig. 3 is a perspective view of trocar assembly with spring penetrating apex shield.

Fig. 4 is a perspective view of distal part of trocar assembly of the Fig. 3.

Fig. 5 is a longitudinal section of trocar assembly of the Fig. 4 and demonstrates penetrated apex shield in extended position.

Fig. 6 is a longitudinal section of trocar assembly of the Fig. 4 and demonstrates penetrated apex shield in retracted position.

Fig. 7 is a perspective view of trocar assembly with groove penetrating apex shield.

Fig. 8 is a longitudinal section of distal part of trocar assembly of the Fig. 7 with groove shield in extended position.

Fig. 9-11 are sections of trocar assembly of the Fig. 8 on the levels 9-9, 10-10, 11-11, respectively.

Fig. 12 is a longitudinal section of distal part of trocar assembly and groove shield of the Fig. 8.

Fig. 13 is a longitudinal section of distal part of trocar assembly of the Fig. 7 with groove shield in retracted position.

Fig. 14 is a longitudinal section of distal part of trocar assembly and groove shield of the Fig. 13.

Fig. 15 is a perspective view of trocar assembly with tubular shield and locking means for it.

Fig. 16 is a longitudinal section of device of the Fig. 15.

Fig. 17 is a perspective top view of trocar unit of trocar assembly of the Fig. 15.

Fig. 18 is a longitudinal section on level 18-18 of the trocar assembly of the Fig. 17.

Fig. 19 is a perspective view of trocar assembly with two independent tubular shields.

Fig. 20 is a left-hand view of device of the Fig. 19.

Fig. 21 is a longitudinal section of device of the Fig. 19.

Fig. 22 is a longitudinal view of trocar unit of device of the Fig. 21.

Fig. 23 is a perspective view of the trocar unit of the Fig. 22.

Fig. 24-29 demonstrate successive changes in mutual positions of the shields at the stages of trocar penetrating end passing through body cavity wall.

Fig. 30 is a perspective view of trocar assembly with low profile protector.

Fig. 31 is a knife-side view of distal part of trocar assembly of the Fig. 30.

Fig. 32 is a left-hand view of the trocar assembly of Fig. 30.

Fig. 33 is a protector-side view of distal part of trocar assembly of the Fig. 30.

Fig. 34 is a longitudinal section of distal part trocar assembly of the Fig. 33.

Fig. 35 is a longitudinal section of the distal part of trocar assembly of the Fig. 33 with protector displaced to retracted position.

Fig. 36 is a perspective view of trocar assembly with blunt penetrating apex.

Fig. 37 is a distal part of device of the Fig. 36.

Fig. 38 is a top view of device of the Fig. 36.

Fig. 39 is an enlarged view of distal part of device of the Fig. 38.

Fig. 40 is a fragment of blunt penetrating apex.

Fig. 41 is a perspective view of trocar assembly with low profile inverted shield.

Fig. 42 is left-hand view of device of the Fig. 41.

Fig. 43 is a top view of distal part of device of the Fig. 41.

Fig. 44 is a knife-side view of distal part of device of the Fig. 41.

Fig. 45 is a shield-side view of distal part of device of the Fig. 41.

Fig. 46 is a longitudinal view of device of the Fig. 41.

Fig. 47 is a view of trocar unit of device of the Fig. 41.

Fig. 48 is a longitudinal section of distal part of device of the Fig. 41 with shield in extended position.

Fig. 49 is a longitudinal section of distal part of device of the Fig. 41 with shield between extended and retracted positions.

Fig. 50 is a longitudinal section of distal part of device of the Fig. 41 with shield in retracted position.

Fig. 51 is a perspective view of trocar assembly with two independent low profile inverted shields.

Fig. 52 is a left-hand view of device of the Fig. 51.

Fig. 53 is an enlarged distal part of device of the Fig. 51.

Fig. 54 is a longitudinal section of distal part of device of the Fig. 51.

Fig. 55 is a distal part of device of the Fig. 51 with shields between extended and retracted positions.

Fig. 56 is a longitudinal section of device of the Fig. 55.

Fig. 57 is a distal part of the device of the Fig. 51 with shield in retracted position.

Fig. 58 is a longitudinal section of device of the Fig. 57.

Fig. 59 is a perspective view of safety trocar with three independent shields.

Fig. 60, 61 are views of distal part of device of the Fig. 59 from knife- and shield-side, respectively.

Fig. 62 is a longitudinal section view of distal part device of the Fig. 59.

Fig. 63 is a longitudinal section view of distal part device of the Fig. 59 with plated shield in retracted position.

Fig. 64-72 demonstrate positions of shields at various penetration stages of the distal part of Fig. 59 device through body cavity wall.

Fig. 73 is a perspective view of trocar assembly, wherein cutting elements in distal and proximal parts have dissimilar sharpness.

Fig. 74 is a distal part of device of the Fig. 73.

Fig. 75 is a top view of device of the Fig. 73.

Fig. 76 is a distal part of device of the Fig. 75.

Fig. 77 is a perspective view of trocar assembly, wherein proximal bias members of lateral shields are made more rigid than distal ones.

Fig. 78 is a knife-side view of distal part of device of the Fig. 77.

Fig. 79 is a shield-side view of distal part device of the Fig. 77.

Fig. 80 is a longitudinal section view of device of the Fig. 79.

Fig. 81 is a longitudinal section view of device of the Fig. 79 with plated shield in retracted position.

Fig. 82 is a perspective view of trocar assembly with low profile inverted stepwise shield.

Fig. 83-85 demonstrate the displacement stages of shield of device of the Fig. 82 from extended to retracted position.

Fig. 86 is a perspective view of trocar assembly, wherein tubular cannula has sloping edge and cutting means situated at least partially at the sloping edge level.

Fig. 87 is a distal part of device of the Fig. 86.

Fig. 88 is a top view of device of the Fig. 86.

Fig. 89 is a distal part of device of the Fig. 88.

Fig. 90 is a longitudinal section view of trocar assembly with mounting means.

Fig. 91-93 are sectional views of device of the Fig. 90 at 91-91, 92-92, 93-93 levels, respectively.

Fig. 94 is a longitudinal section view of portal unit of device of the Fig. 90.

Detailed Description of Preferred Embodiments

Safety trocar assembly is intended for making orifices in body cavity wall and generation of conditions for subsequent introduction of instruments into a body cavity.

Before addressing specific implementations of the present invention in detail, it should be noted that the invention will be presented with reference to numerous examples, each of which illustrates one or more preferred feature of the invention. These various preferred features may each be used individually to advantage with an otherwise conventional trocar. In most preferred implementations, however, multiple preferred features are combined to provide a trocar with greatly enhanced levels of safety to the patient and/or professional staff, and/or to provide numerous other advantages as will become clear from the following description.

Turning now to the Figures, Figs. 1 and 2 illustrate a first embodiment of a trocar assembly 1 in which a retractable shield 14 is deployed to selectively shield only the distal portion of a penetrating end 10. As a result, the shield extends itself as soon as the distal portion clears the tissue wall, well before full penetration of end 10 occurs. Preferably, the distal portion extends for less than about half of the axial length of the cutting elements measured parallel to the axis, and most preferably, no more than about a third of the length. Radially, shield 14 typically has a diameter of between about 3 and about 6 mm.

More specifically, Fig. 1 shows trocar assembly 1, comprising trocar unit 2 and portal unit 3. Fig. 2 shows a longitudinal section of trocar assembly 1 in enlarged scale. Portal unit 3 has tubular cannula 4, portal housing 5 and inner seals 6, 7 located in portal housing 5 and aimed to maintain insufflation of the body cavity. Tubular cannula 4 has an open distal end 8. Trocar unit 2 has elongated obturator 9 adapted to be removably inserted through cannula 4 and having a penetrating end 10 exposed through cannula 4 open distal end 8. Penetrating end 10 has penetrating apex 11 and a sloping side wall 12. Longitudinal opening 17 of obturator 9 houses protector means 13 comprising tubular penetrating apex shield 14 adapted to actuate between a retracted position and an extended position (shown in Fig. 2), when shield 14 surrounds penetrating apex 11, and sloping side wall 12 surrounds shield 14 from the outside. Distal edge 15 of shield 14 forms uninterrupted hedge. Protector means 13 comprises bias means made as a compression spring 16. In the embodiment shown in Figs. 1, 2 penetrating apex 11 formed by

pointed distal edge of cylindrical piece 18, having circular ledge 19 which is abutted by circular ledge 20 of penetrating apex shield 14, when shield 14 reaches its extended position. Stopper bushing 21 abutted by spring 16 is tightly placed on proximal end of cylindrical piece 18.

Device 1 is operated as follows:

Surgeon holds device 1 by housing 5 and push member 22 situated on obturator 9 proximal end. Device 1 is oriented approximately perpendicular to body cavity wall and is pressed to it, applying pushing effort to push member 22. The resistance force of pierced tissues applied to shield distal edge 15, displaces shield 14 towards retracted position so that penetrating apex 11 strips bare and pierces body cavity wall tissues. In this process, shield uninterrupted distal edge 15 forms a hedge precluding the introduction and engagement of tissue fibers of body cavity wall between shield 14 and penetrating apex 11, thus ensuring smooth motion of device 1 through the tissues. When penetrating apex 11 and shield distal edge 15 have entered a patient's body cavity, however, before penetrating end 10 has been fully inserted, the force applied to shield distal edge 15 is removed, and spring 16 returns shield 14 to extended protected position, and further movement of penetrating end 10 to body cavity occurs with protected penetrating apex 11, which precludes the injury of inner organs. Penetrating apex 11 can have diversified shapes, for instance, conical or pyramidal one, with cutting edges (not shown in the Fig.).

Turning now to Figures 3-6, these illustrate a variant of the embodiment of Figures 1 and 2 in which the shield is implemented as a helical coil of resilient wire formed with a closed portion 114 acting as the shield and a spring portion 116 which provides forward biasing. In other respects (preferred dimensions etc.), this implementation is similar to the previous embodiment. More specifically, Fig. 3 shows safety trocar assembly 101, comprising trocar unit 102 and portal unit 103.

Fig. 4 shows distal part 123 of device 101 in enlarged scale, and Fig. 5 shows a longitudinal section of distal part 123. Penetrating end 110, protruding through cannula 104 open distal end 108, has penetrating apex 111 made integral with obturator 109, penetrating apex shield 114, and bias means made as a compression spring 116. In this, shield 114 and spring 116 are made as a single piece from coiled springy rod fixed in obturator 109 circular groove 124. Penetrating end 110 also has sloping side wall 112, whereon outer cutting means 125, 126 made as outer

cutting members are located, and which can be made of the same material as obturator 109.

Fig. 4, 5 show shield 114 in extended protected position.

Fig. 6 shows shield 114 in retracted position.

Trocar assembly 101 operates similarly to trocar assembly 1.

Turning now to Figures 7-14, these illustrate a similar concept as applied to a penetrating end formed as a flat knife. Specifically in relation to configurations employing cutting edges provided by flat blades, it is preferred that the shield element(s) are formed as low-profile shields in a manner that they experience very low resistance to returning to their distal protective positions almost immediately that the cutting edge clears the tissue wall.

In order to better define the preferred geometrical features which ensure this rapid return of the shield to its operative position, reference will be made in the description and claims to various terminology which is defined as follows:

- the "displacement vector" of a shield is the direction defining its retraction between its extended and retracted positions. This direction generally lies in a plane parallel to the longitudinal axis of the trocar assembly;
- the "cutting plane" is a plane defined by a cutting edge of the flat blade and the central longitudinal axis of the device;
- the "shield height" is the distance between the cutting plane and the outer surface of the shield as measured perpendicular to said cutting plane;
- the "shield width" is the maximal distance between the longitudinal axis of the device and the outer surface of the shield;
- the "local comparative height" of the shield is the ratio of local maximal height of the shield to the local maximal width of the shield measured in a common plane perpendicular to the device longitudinal axis;
- the "proximal protected position" of the shield is the extreme proximal position of the shield which offers complete protection of the cutting edge; and
- the "screen area" of the shield is the section of the shield which, when the shield is located in the proximal protected position, is situated between two planes perpendicular to the device longitudinal axis so that one of the planes intersects the proximal end of the cutting edge, whereas the other the plane intersects distal end of the cutting edge, and

the plane equidistant from both the perpendicular planes divides the screen area into proximal and distal screen zone.

In the case of a shield located on both sides of a flat blade such as is shown here, reference is also made to a "full local comparative height" of the shield defined as the ratio of total local maximal height of the shield and the local maximal width, wherein the total local maximal height of the shield is the distance between outer surfaces of opposite parts of the shield measured perpendicular to the cutting plane.

According to these definitions, in the case of a two-sided shield, it is particularly preferred that the full comparative height of the shield along the proximal screen area is below 1.4.

Turning now to the structural details of this embodiment, Fig. 7 shows a safety trocar assembly 201, comprising trocar unit 202 and portal unit 203.

Fig. 8 shows longitudinal section of obturator 209 distal part 227 in enlarged scale.

Obturator distal part 227 comprises penetrating apex 211 with penetrating apex cutting means looking like distal knife 228 and outer cutting member looking like proximal knife 225. Both knives - 228, 225 – are made on the plate-shaped base 229, which has two springy arms 230, 231 with ledges 232, 233 in its proximal section, said ledges ensuring engagement of plated base 229 and obturator 209. Penetrating apex shield 214 is made as two-sided low profile shield and has longitudinal slot 234 plate base 229 passes through. Bias means is made as a compression spring 216, which abuts shield 214 with its distal face 235, whereas its proximal one abuts plate-shaped base 229. In Figs. 7, 8, 12 shield 214 is in extended position so that its further distal displacement is limited by ledge 219 on plate-shaped base 229, which is abutted by shield 214 ledge 220. In Figs. 13, 14 shield 214 is in retracted position.

Device 201 operates similarly to device 1.

Turning now to Figures 15-18, a locking mechanism according to the present invention will now be described. The lock mechanism is configured to prevent retraction of a retractable shield while the obturator is removed from the trocar, thereby protecting professional staff from accidental injury. The lock mechanism is released automatically by insertion of the obturator within the trocar, thereby allowing unimpeded retraction of the shield as required. It will be noted that this lock mechanism may be used to advantage with an otherwise conventional shield as shown here, of in combination with the preferred shield structures of the present

invention, as will be illustrated below.

Figs. 15, 16 show a safety trocar assembly 301 with lock means 335 for shield 336 of penetrating end 10. Device 301 comprises trocar unit 302 and portal unit 303. Portal unit 303 has tubular cannula 304 and portal housing 305. Portal housing 305 has inner seals 306 and 307 to maintain insufflation of body cavity, seal member 307 being made as O-ring, and seal member 306 as flapped valve. Trocar unit 302 has obturator 309 comprising distal part 327 and proximal part 338.

Shield 336 is made tubular and has rest ring 339. Bias spring 351 is situated between said rest ring 339 and obturator 338 proximal section.

Lock means 335 has obturator-situated controlling member 340, partially protruding laterally of obturator distal part 327 and adapted to the interaction with inner surface 341 of tubular cannula 304. Controlling member 340 is made integral with abutting member 342, having abutting surface 343. Abutting member 342 by dint of springy legs 344, 345 is spring-loaded to obturator 309.

Fig. 17 shows top view of trocar unit 302. Fig. 18 shows longitudinal section view of trocar unit 302 of Fig. 17. In Figs. 17, 18 lock means 335 is in lock position and locks shield 336 in protected position.

Shield 336 wall has elongated through slot 346 with two areas of different width – slot distal area 347 is narrower than the slot proximal area 448. Controlling member 340 has width less than that of slot distal area 347, whereas abutting member 342 is wider than slot distal area 347 but narrower than slot proximal area 348.

Therefore, when trocar unit 302 is outside portal unit 303 (Figs. 17, 18), legs 344, 345 shift abutting member 342 to lock position, in which abutting member 342 enters slot proximal area 348, and abutting surface 343 is set opposite of ledge 349 formed by the transition of slot narrow area 347 to slot wide area 348, thus precluding shield 336 proximal displacement.

Unlocking of shield 336 occurs when trocar unit 302 enters portal unit 303, but only after protected penetrating end 310 intersects distal inner seals 306, 307 so that controlling member 340 is resisted by cannula inner surface 341 and shifts abutting member 342 from the zone of its interaction with shield 336.

Device 301 operates similarly to device 1.

Turning now to Figs. 19-29, these illustrate a particularly preferred embodiment which combines a distal-portion shield of the type illustrated in Figures 1 and 2 with a locking mechanism of the type illustrated in Figures 15-18.

In a further preferred feature, which may be used either alone or in combination with the locking mechanism, the distal-portion shield is combined with a conventional large-diameter shield, in this case formed as concentric cylinders, to provide two-stage protection. The distal-portion shield provides immediate protection as soon as the distal portion of the penetrating end clears the tissue wall (Fig. 27), while the large-diameter shield provides additional protection once the penetrating end is fully inserted (Fig. 29). In the most preferred implementation shown here, the locking mechanism is operative to lock both shields when the obturator is removed.

More specifically, Figure 19 shows safety trocar assembly 401 with mutually independent shields 414, 436. Device 401 comprises trocar unit 402 and portal unit 403. Portal unit has tubular cannula 404 and portal housing 405.

Fig. 20 shows a left-hand view of device 401.

Fig. 21 shows a longitudinal section view of device 401.

Trocar unit 402 has obturator 409 comprising distal part 427 and proximal part 438. Penetrating end 410 comprising penetrating apex 411, sloping side wall 412 and outer cutting members 425, 426 450 with cutting edges 451 protruding above the sloping side wall 412 level. There are two tubular shields: penetrating apex shield 414 and outer shield 436. There are two independent, separate for both shields 414 and 436 bias means made as compression springs 416, 451. There is common for both shields 416, 436 lock means 435 comprising obturator-situated controlling member 440, partially protruding laterally of obturator distal part 427, and adapted to the interaction with inner surface 441 of tubular cannula 404. Controlling member is made integral with abutting member 442, having outer abutting surface 443 and inner abutting surface 452. Abutting member 442 by springy legs 444, 445 is spring-loaded to obturator 409.

Fig. 22 shows a longitudinal section of trocar unit 402 of device 401.

Fig. 23 shows top view of trocar unit 402.

In Fig. 22, 23 lock means 435 is in lock position and locks shields 414 and 436 in protected position. Shield 436 wall has through elongated slot 446 with two different-width sections – distal section 447 is narrower than proximal section 448. Controlling member 440 has width

less than that of slot 447 distal section, whereas abutting member 442 is wider than distal section 447 but narrower than slot 448 proximal section.

When trocar unit 402 is outside portal unit 403 (Figs.22, 23), legs 444, 445 shift abutting member 442 to the lock position, when abutting member 442 partially enters slot 446 proximal section 448, and outer abutting surface 443 is set opposite of ledge 449 on outer shield 436, precluding shield 436 distal displacement, and inner abutting surface 452 is set opposite of proximal face 453 of penetrating apex shield 414, also precluding shield 414 proximal displacement. Unlocking of both shields 414, 436 occurs with trocar unit 402 entering portal unit 403, which takes place when controlling member 440 interacts with cannula 404, and thus forces abutting member 442 out of interaction zone with shields 414, 436.

Figs. 24-29 show operating shields on successive stages of penetrating end 410 passing through body cavity wall 454.

Fig. 24 shows starting moment of trocar assembly 401 interaction with body cavity wall, when outer shield 436 is between its extended and retracted positions, penetrating apex shield 414 is in retracted position, and penetrating apex 411 has incorporated into body cavity wall 454.

Fig. 25 shows the moment when both shields 414, 436 are forced out by body cavity wall tissue to retracted position.

Fig. 26 shows the moment when both shields 414, 436 are in retracted position, and penetrating apex 411 has penetrated into body cavity.

Fig. 27 shows the moment immediately after the displacement of penetrating apex shield 414 to extended protected position. In this process, outer cutting members 426, 426, 450 continue cutting tissue.

Fig. 28 shows the moment before shield 436 operation.

Fig. 29 shows both shields 414, 436 in extended position.

As can be seen, independent performance of shields 414 and 436 greatly ensures trocar safe operation.

Turning now to Figs. 30-35, these show a further embodiment of the present invention as applied to an obturator 509 with a distal knife 528. In this case, a one-sided low profile shield 514 is used. Since the cross-sectional area of the shield adds relatively little to the cross-sectional area of the knife itself, the shield advances through the incision to its distal position to

provide protection almost immediately on penetration of the tissue wall. Preferably, according to the terminology defined above, the shield local comparative height along the proximal screen area for a one-sided shield is below 0.8.

Fig. 30 shows safety trocar assembly 501 with one-sided low profile shield 514. Device 501 has trocar unit 502 and portal unit 503. Portal unit 503 has cannula 504 and portal housing 505.

Fig. 31 shows the view of device distal part 523 from the side of penetrating apex cutting means made as distal knife 528.

Fig. 32 shows left-hand view of device 501.

Fig. 33 shows device distal part 523 from the side of shield 514..

Fig. 34 shows longitudinal section of device distal part 523 when shield 514 is in extended position.

Trocar unit 502 has obturator 509 with penetrating end 510 with sloping side wall 512 and outer cutting members 525, 526 so that outer cutting members 525, 526 are made integral with obturator 509. Indented distal knife 528 is made on plate-shaped base 529, and has one-sided low profile shield 514 with bias means made as compression spring 516.

When penetrating end 510 passes through body cavity wall, the tissue resistance force shifts shield 514 to retracted position (Fig. 35), and stripped knife 528 makes an orifice in the tissue. Low profile protectors, both one-sided, and two-sided – are the protectors against instantaneous operation, i.e. they operate upon knife minimal penetration to body cavity.

Turning now to Figures 36-40, these illustrate an alternative principle which may be used to avoid injury to internal organs by combining a relatively small blunt apex with one or more blade following proximally thereof. When used to penetrate the fixed wall of the abdomen, the blunt apex forces apart the tissue to initiate penetration, while the following blades enlarge the incision to the extent required. With respect to the more mobile internal organs, the blunt apex pushes aside the organs without causing damage.

Fig. 36 shows a safety trocar assembly 601 with blunt apex 655. Device 601 comprises trocar unit 602 and portal unit 603. Trocar unit 602 comprises obturator 609 with penetrating end 610. Penetrating end 610 has sloping side wall 612, cutting means made as cutting arrisis 625, 626 of penetrating end 610 material. Distally of cutting arrisis 625, 626 there is a blunt apex 655. The blunt apex sizes are chosen so that it passes through body cavity wall tissues with slight

resistance, and entering a body cavity, for instance, abdominal cavity, it draws movable organs – intestinal loops, big epiploon – aside, without injuring them. Therewith, blunt apex tip 656 can be rounded with rounding radius within 0.5 to 2.5 mm. However, the preferential rounding radius is within 0.75-1.5 mm.

The blunt apex motion effort through tissue can be diminished if blunt apex 657 is made pointed (Fig. 40), but the meeting angle for surfaces 658, 659 should be above 90 degrees, preferentially above 120 degrees. In such embodiment apex retains its function of blunt apex, i.e. it preserves all the benefits of rounded blunt apex 656 with facilitated passing through tissue.

Figures 41-50 show a further embodiment which supplements the embodiment of Figures 36-40 with shields for the lateral blades. Advantageously, the shield may be formed in such a manner as to provide protection for the distal portion of the blade while the proximal portion is still operative, thereby providing enhanced protection.

Fig. 41 shows safety trocar assembly 701 with one-sided low profile inverted shield 736.

Device 701 has trocar unit 702 and portal unit 703. Portal unit 703 has cannula 704 and portal housing 705. Trocar unit has obturator 709 (Fig. 43 – top view of device 701 distal part 723) with penetrating end 710. Penetrating end 710 comprises blunt apex 755, sloping side wall 712, two knives 725, 725 and inverted shield 736.

Fig. 44 shows device distal part 723 from the side of knives 725, 726,

Fig. 45 shows device distal part 723 from the side of shield 736.

Fig. 46 shows longitudinal section of device 701.

Fig. 47 shows longitudinal section of device 701 trocar unit 702. Trocar assembly 701 has lock means 735 for shield 736. Lock means 735 has obturator-situated controlling member 740, partially protruding laterally of obturator 709 and adapted to the interaction with inner surface 741 of cannula 704. Controlling member 740 is made integral with abutting member 742, having abutting surface 743. Abutting member 742 is spring-loaded to obturator 709 by springy legs 744, 745. Shield 736 has abutting bar 758. When trocar unit 702 (Fig. 47) is outside the portal unit 703, legs 744, 745 shift abutting surface 743 to the level of abutting bar 758, and such mutual disposition of shield 736 and lock means 735 is the lock position which prevents shield 736 proximal displacement.

Unlocking of shield 736 takes place when trocar unit 702 is introduced to portal unit 703 but only after protected penetrated end 710 passes through distal inner seals 706, 707 so that controlling member 740, being resisted by cannula 704 inner surface 741, shifts abutting member 742 from the interaction zone with abutting bar 758.

Figs. 48, 49, 50 show longitudinal section of device 701 distal part 723 in enlarged scale at shield 736 various performance stages.

Fig. 48 shows shield 736 in extended position. Shield 736 is made plated and besides abutting bar 758 has protection edges 759, 760, guiding slots 761, 762, through which cotters 763, 764 are passing, window 765, wherein bias compression spring 716 is mounted, whose distal end abuts shield 73, whereas proximal end 766 is fixed to plate-shaped base 729 of knives 725, 726. Shield 736 is an inverted shield which means that when it shifts from extended position to retracted position, the opening of knives 725, 725 starts from their proximal sections 767, 768. This operation mechanism of shield 736 is achieved owing to the fact that relative to the device longitudinal axis the incidence angle of the line connecting distal point 769 and proximal point 770 on protection edge 759 is more acute than the incidence angle of the line connecting distal and proximal points 771, 772 on knife 725.

Fig. 50 shows shield 736in retracted position. Consequently, as penetrating end 710 enters body cavity, closing of knives 725, 726 starts from their distal sections which ensures low injury level.

The embodiment of Figures 51-58 generally parallels the embodiment of Figures 41-50, but provides independently operative shields for the lateral blades. Thus, Fig. 51 shows a safety trocar assembly 801 with two independent low profile inverted shields 836, 871. Device 801 comprises trocar unit 802 and portal unit 803. Portal unit 803 comprises cannula 804 and housing 805.

Fig. 52 shows left-hand view of device 801 in enlarged scale.

Fig. 53 shows device 801 distal part 823 in enlarged scale. Trocar unit 802 comprises obturator 809 with penetrating end 810 which is formed by blunt apex 855, sloping side wall 812, with protection edges 859, 860 of shields 836, 871, and knives 825, 826 protruding above it. Shields 836, 871 are made plated and equipped with independent bias compression springs 816, 851. Knives 825, 826 (Fig. 56) are made on plate-shaped bases 829, 872.

Figs. 54-58 show mutual arrangement of knives 825, 826 and shields 836, 871 at various operation stages of shields 836, 871. Fig. 54 shows both shields 836, 871 in extended-protected position. Figs. 55, 56 show shields 836, 871 in intermediate position between extended and retracted position, when only proximal sections 867, 868 of knives 825, 826 are open. Figs. 57, 58 show shields 836, 871 in retracted position, when both knives 825, 826 are open along their entire lengths.

Figs. 54-58 show symmetrical operation of shields 836, 871, but inasmuch as shields 836, 871 are made independent and are equipped with independent bias springs 816, 851, so the operation of shields 836, 871 can be independent , non-simultaneous (not shown on Figs.). The operation non- simultaneity stems from resistance non-simultaneity of tissue elements of body cavity wall. That is the concept of independent shields permits to take into account and to respond automatically to local properties of tissues.

However, for the surgeon the mode of device 801 operation does not differ from that of similar alternative devices.

Figures 59-72 illustrate an alternative type of shield for lateral blades, in this case combined with a distal knife and shield similar to those of Figures 30-35. The lateral shields are here implemented as resilient elements which react substantially independently to force applied near their distal and proximal ends. As a result, this configuration also provides protection for the distal portion of the blades while the proximal portion is still operative (Figures 70 and 71).

Fig. 59 shows perspective view of safety trocar assembly 901 comprising trocar unit 902 and portal unit 903. Portal unit 903 has cannula 904 and housing 905. Trocar unit has obturator 909 with penetrating end 910. Penetrating end is formed by sloping side wall 912, penetrating means 973 for orifice formation in body cavity wall, and protector means 913 for said penetrating means 973. Penetrating means 973 comprises penetrating zones formed by knives 928, 925, 967, 926, 968 made on common plate-sided base 929 (Fig. 62) so that knives 925 and 967, as well as knives 926 and 968 have cutting edges confluent with one to another. Each penetrating zone has protector member, and each protector member has its own bias member. For penetrating zone 928 made as indented knife, protector member is made as plane-shaped shield 914, whereas bias member as compression spring 916.

Protector members 969 and 970 of knives 925, 967 have bias means 951, 979, respectively, so

that protector members 969, 970 are made as a common shield 936. Common shield 936 and bias means 951, 979 are made as a single resilient part, having a slat 980, which in extended position (Figs. 60, 61, 62) is situated parallel to cutting edge of knives 925, 967, and bias means 951, 979 made as resilient elements, each of them being connected to slat 980 by one its end 981, 982, whereas the other one 983, 984 is connected to the plate-shaped base 929. Protector members 985 and 986 of knives 926 and 968 have bias means 987, 988, respectively, so that protector members 985, 986 are made as a single resilient part, having a slat 990 which in extended position is situated parallel to cutting edges of knives 926, 968, and bias means 987, 988 are made as resilient elements, each of them being connected to slat 980 by one its end 991, 992, whereas the other ones 993, 994 are connected to the plate-shaped base 929.

Figs. 64-72 show mutual arrangement of protector members at various stages of penetrating end 910 passing through body cavity wall 954.

Fig. 64 shows shields 914, 936, 989 in extended position.

Fig. 65 shows shield 914 in retracted position, and open knife 928 creates an orifice in body tissue.

Fig. 66 shows protector members 969, 985 displaced to retracted position, and knives 925, 926 create orifice in body tissue.

Fig. 67 shows all shields 914, 936, 989 in retracted positions.

Fig. 68 shows knife 928 entry to body cavity.

Fig. 69 shows the point immediately after shield 914 displacement to extended protected position.

Fig. 70 shows knives 925 and 926 entry to body cavity, one of them 925 being shown protected by protector member 969, which displays independent operation of symmetrical protector members 969 and 985, thus ensuring maximal fast operation of protector members, and, consequently, minimal injury of internal organs.

Fig. 71 shows protector members 914, 969, 985 in extended-protected position.

Fig. 72 shows penetrating end 910 as totally entering the body cavity, with totally protected penetrating means.

Figures 73-76 illustrate a configuration generally similar to that of Figures 36-39 but wherein

the lateral blades are formed with graduated sharpness decreasing from distal to proximal. This helps to prevent over-broadening of an incision during insertion. Thus, Fig. 73 shows a safety trocar assembly 1001 comprising trocar unit 1002 and portal unit 1003. Portal unit 1003 has cannula 1004 and housing 1005. Trocar unit 1002 has obturator 1009 with penetrating apex 1010. Penetrating apex 1010 is formed by blunt apex 1055, sloping side wall 1012, and cutting means. Cutting means is made as two sharpened protrusions 1025, 1026 on sloping side wall 1012 so that protrusions 1025, 1026 are made with decreasing proximal sharpness, which ensures tissue cutting at the proximal

level of protrusions 1025, 1026 at higher tissue tension than by tissue cutting at the distal level of protrusions 1025, 1026. Such mechanism of tissue cutting precludes generation of excessive diameter orifice in body cavity wall.

Figures 77-81 show an embodiment generally similar to that of Figures 59-72, but wherein the resilient elements are formed with greater spring resistance at their rear proximal end than at their distal end, thereby also tending to preclude over-widening of the incision.

Fig. 77 shows a safety trocar assembly 2001 comprising trocar unit 2002 and portal unit 2003. Portal unit 2003 has cannula 2004 and housing 2005. Trocar unit has obturator 2009 with penetrating end 2010. Penetrating end is formed by sloping side wall 2012, penetrating means 2073 for orifice formation in body cavity wall, and protector means 2013 for said penetrating means 2073. Penetrating means 2073 comprises penetrating zones formed by knives 2028, 2025, 2067, 2026, 2068 made on common plate-sided base 2029 (Fig.78) so that knives 2025 and 2067, as well as knives 2026 and 2068 have cutting edges confluent into each other. Each penetrating zone has protector member, and each protector member has its own bias member. For penetrating zone 2028 made as indented knife, protector member is made as plate-shaped shield 2014, and bias member is made as compression spring 2016.

Protector members 2069 and 2070 of knives 2025, 2067 have bias means 2056, 2079, respectively, so that protector members 2069, 2070 as made as a common shield 2036. Common shield 2036 and bias means 2051, 2079 are made as a single resilient part, having a slat 2080, which in extended position (Figs. 77, 78) is situated parallel to cutting edges of knives 2025, 2067, and bias means 2051, 2079 are made as resilient elements, each of them being connected to slat 2080 by one its end 2081, 2082, whereas the other one 2083, 2084 is

connected to the plate-shaped base 2029. Protector members 2085 and 2086 of knives 2026 and 2068 have bias means 2087, 2088, respectively, so that protector members 2085, 2086 are made as a common shield 2089. Common shield 2089 and bias means 2087, 2088 are made as a single resilient part, having a slat 2090, which in extended position is situated parallel to cutting edges of knives 2026, 2068, and bias means 2087, 2088 are made as resilient elements, each of them being connected to slat 2090 by one its end 2091, 2092, whereas the other ones 2093, 2094 are connected to the plate-shaped base 2029. In this, proximal bias means 2079 is made more rigid than distal bias means 2051, consequently, the displacement of proximal protector member 2070 and knife 2067 opening, and further on, tissue cutting at this level of penetrating means occurs at higher tissue tension than by tissue cutting at the level of knife 2025.

Shield 2089 operates in similar manner.

Such tissue cutting mechanism precludes generation of excessive diameter orifice in body cavity wall.

Figures 82-85 show an embodiment generally similar to that of Figures 41-50, in which the shield is formed with a stepped edge. The inclination of the steps to the longitudinal axis of the assembly varies from greatest at the distal part of the shield to least at the proximal part of the shield. This tends to ensure that less force is required to cause retraction of the shield at smaller diameters of hole than at large diameters, thereby limiting over-widening of the incision. Thus, Fig. 82 shows safety trocar assembly 3001 with low profile inverted shield 3036. Device 3001 has trocar assembly 3002 and portal assembly 3003. Portal assembly 3003 has cannula 3004, and housing 3005. Trocar assembly has obturator 3009 with penetrating end 3010 formed by blunt apex 3055, and sloping side wall 3012, with protector edges 3059, 3060 of shield 3036 and knives 3025, 3026 protruding over it.

Trocar assembly 3001 has lock means 3035 for shield 3036. Lock means 3035 has obturator-situated controlling member 3040, partially protruding laterally of obturator 3009, and adapted to the interaction with inner surface 3041 of cannula 3004. Controlling member 3040 is made integral with cutting member 3042, having abutting surface 3043. Abutting member 3042 by springy legs 3044, 3045 is spring-loaded to obturator 3009. Shield 3036 has abutting bar 3058. When trocar unit 3002 is outside portal unit 3003, legs 3044, 3045 shift abutting surface 3043

to the level of abutting bar 3058, and such mutual arrangement of shield 3036 and lock means 3035 is the lock position (not shown in the Fig.), wherefrom shield 3036 proximal displacement is impossible.

Figs. 83, 84, 85 show longitudinal section of device 3001 distal part 3023 in enlarged scale at various stages of shield 3036 operation.

Fig. 83 shows shield 3036 in extended position. Shield 3036 is made plated and has, in addition to abutting bar 3058 and protection edges 3059, 3060, guiding slots 3061, 3062, through which cotters 3063, 3064 are passing, window 3065, wherein bias compression spring 3016 is mounted, abutting shield 3036 by its distal end, and fixed to plate-shaped base 3029 by its proximal end.

Fig. 83 shows shield 3036 in the position intermediate between extended and retracted ones.

Fig. 84 shows shield in retracted position.

Protector edges 3059, 3060 are made stepwise with varying slope of steps 3095 so that in distal-proximal direction the slope of steps 3095 relative to device 3001 longitudinal axis decreases, and, consequently, in the same direction decreases the force of steps 3095 engagement with the tissue, hence, larger tension is required for shield 3036 proximal displacement upon tissue interaction with proximal steps than it is for tissue interaction with distal steps, and hence, cutting of tissue at the level of distal sections 3025, 3026 occurs with smaller tissue tension than at the level of proximal sections of knives 3025, 3026. Such tissue cutting mechanism precludes generation of excessive diameter orifice in body cavity wall.

Figures 86-89 illustrate a further principle of the present invention, useful either alone or in combination with other features described above. According to this feature, the cannula is configured to provide a distally projecting portion which is co-extensive in the axial direction with at least one cutting edge of the obturator. As a result of this structure, the projecting portion of the cannula is already located within the incision while the cutting process is still progressing, thus ensuring that the size of the incision accommodates the lateral dimensions of the cannula without causing further damage to the tissue by forced insertion through an undersized incision.

Fig. 86 shows a perspective view of trocar assembly 4001. Device 4001 has trocar unit 4002 and portal unit 4003. Portal unit 4003 has housing 4005 and tubular cannula 4004. Cannula has

open distal end 4008, having sloping edge 4036. Trocar unit 4002 has obturator 4009 with penetrating end 4010, whereon knife 4025 is situated so that knife 4025 proximal end 4067 is located proximally of distal point 4097 of sloping edge 4096. With such mutual arrangement of sloping edge 4096 and knife 4025 maximally non-injurious advance of penetrating end through body tissues takes place, as knife 4025 cuts tissues stretched by sloping edge 4096, thus precluding their rupture.

Fig. 90 shows trocar assembly 5001 with mounting means 5098. Device 5001 has trocar assembly 5002 and portal unit 5003. Trocar asembly 5002 has obturator 5009 with penetrating end 5010. Portal unit 5003 has tubular cannula 5004, housing 5005, inner seals 5006, 5007, and mounting means 5098. Mounting means 5098 comprise inflated cuff 5099 mounted on cannula 5004, connector 5100 with rebound valve 5101, passage 5102 made in cannula 5004 wall and connecting connector 5100 with cuff 5099. Mounting means 5098 also has outer mounting means comprising restraining member 5103 movable along cannula 5004, and resistance means precluding spontaneous proximal displacement of restraining member 5103. Restraining member 5103 has a flange 5108 and an orifice 5104 the cannula 5004 passes through. Resistance means is made as an engagement protrusion: cannula engagement protrusion 5105 and restraining member engagement protrusion 5106. In this embodiment, engagement protrusion 5105 and 5106 are situated spirally, permitting to shift restraining member 5103 along cannula 5004 by its rotation. Device 5001 also has means for gas feeding into body cavity, comprising connector 5107 and passes 5108.

Device 5001 operates as follows.

Fig. 90 shows the device in ready-to-work view, when cuff 5099 is deflated, and restraining member 5103 is in proximal position. Body cavity wall is pierced in usual manner. After cuff 5099 introduction into body cavity, trocar unit 5002 is removed. Cuff 5099 is inflated via connector 5100, and then by drawing housing 5005 inflated cuff 5099 is pressed against body cavity wall 5054, whereas restraining member 5103 is pushed toward cuff 5099 until the restraining member 5103 is pressed against body cavity wall 5054 (Fig. 94). Portal unit 5003 set in this way is well fixed at the body cavity wall 5054, which precludes its accidental displacement during introduction and removal of surgical instruments through portal unit 5003. Compression of body cavity wall tissues between cuff 5099 and restraining member 5103

generates additional hemostasis in cut tissues and serves as a sealing factor, precluding gas leakage out of body cavity through the clearance between cannula 5004 and orifice walls. To remove portal unit 5003 from body cavity wall, cuff 5099 is deflated.

Although the present invention has been shown and described in terms of preferred embodiments, it will be appreciated that various changes and other modifications are contemplated within the spirit and scope of the present invention as defined by the following claims.

Claims:

What is claimed is:

1. A safety trocar assembly comprising:

- portal unit with elongated, tubular cannula having an open distal end;

- trocar unit having elongated obturator adapted to be removably inserted through said cannula and having a penetrating end exposed through said open distal end of said cannula and comprising a penetrating apex mechanical cutting means for making orifice in body cavity wall, and a sloping side wall;

- a protector means situated on said obturator and comprising penetrating apex shield adapted to actuate between a retracted and an extended position, when said shield surrounds said penetrating apex and said sloping side wall surrounds said shield from the outside;

- distal edge of said shield forms a hedge precluding the introduction and engagement of tissue fibers of body cavity wall both between said shield and said penetrating apex, and between said shield segments;

- bias means for biasing said shield toward said extended position and for permitting said shield move to said retracted position in response to a proximally directed force applied to said shield distal edge, said bias means, returning said shield to said extended position when the force applied to said shield distal edge is removed, which occurs when said penetrating apex and said shield distal edge have entered a patient's body cavity, however, before said penetrating end has been fully inserted.

2. Device according to Claim 1, wherein said bias means has means made as spring mounted between said shield and parts of said trocar unit.

3. Device according to Claim 2, wherein said spring is situated in said obturator, preferentially in its distal part.

4. Device according to Claim 1, wherein said shield is tubular.

5. Device according to Claim 3, wherein said shield is made coiled springy rod.

6. Device according to Claim 5, wherein said shield is made integral with said spring.

7. Device according to Claim 1, wherein said penetrating apex is made as a separate part mounted into said obturator.

8. Device according to Claim 1, wherein said penetrating apex is made integral with at least distal part of said obturator.

9. Device according to Claim 1, which has longitudinal central axis and said obturator and tubular cannula are situated coaxially with it.

10. Device according to Claim 9, wherein:

- the displacement vector of said protector means between its said extended and retracted position is in the plane parallel to said longitudinal axis of trocar assembly;

- said cutting means comprises at least one cutting edge situated in the plane parallel to said central longitudinal axis of the device so that this plan is the cutting plane of said cutting edge;

- said protector means has a shield for protecting sai l cutting edge;

- said shield has shield outer surface and as such ser es that section of said shield surface which in the assembled position of said trocar assen bly and when said shield is in said extended position is located distally of said open distal end of tubular cannula and protrudes beyond the bounds of members of said trocar assembly imn ovable relative to said tubular cannula;

- said shield has shield height, and as such serves th distance between said cutting plane and said shield outer surface;

- said shield has shield width, and as such serves the distance between said device longitudinal axis and said shield outer surface;

- said shield has shield local comparative height, an as such serves the ratio of local maximal height of said shield to local maximal width of sai l shield measured in their common

plane perpendicular to said device longitudinal axis;

- said shield has proximal protected position, and as such serves the extreme proximal position of said shield when there is the complete protection of said cutting edge;

- there is a screen area of said shield, and as such serves the section of said shield which, when said shield is located in said proximal protected position, is situated between two planes perpendicular to said device longitudinal axis so that one of said planes intersects the proximal end of said cutting edge, whereas the other said plane intersects distal end of said cutting edge, and the plane equidistant from both said perpendicular planes divides said screen area into proximal and distal screen zone.

11. Device according to Claim 10, wherein said shield has shield zones located bilaterally of said cutting plane;

- there is full local comparative height of said shield, and as such serves the ratio of total local maximal height of said shield and said local maximal width, so that total local maximal height of said shield is the distance between outer surfaces of said shield zones measured along the line perpendicular to said cutting plane.

12. Device according to Claim 10, wherein there is a one- sided low profile shield situated laterally of said cutting plane, and said shield local comparative height along the proximal screen area is below 0.8.

13. Device according to Claim 11, wherein there is a two- sided low profile shield, and said shield full comparative height along the proximal screen area is below 1.4.

14. Device according to Claim 10, wherein said cutting means comprises penetrating apex cutting means situated inside of said penetrating apex shield.

15. Device according to Claim 14, wherein said penetrating apex cutting means are situated uniplanarly, whereas said penetrating apex has elongated transversal cross-section with largest axis lying uniplanarly with said penetrating apex cutting means.

16. Device according to Claim 10, wherein said cutting means has outer cutting means situated outside of said penetrating apex shield.

17. Device according to Claim 13, 16, wherein said penetrating apex cutting means and outer cutting means are made integral on the plate-shaped base, and said penetrating apex shield is made as two-sided low profile shield, and has longitudinal slot, said plate base passes through.

18. Device according to Claim 16, wherein there is at least one outer shield for said outer cutting means adapted to actuate between outer shield retracted - unprotected - position and outer shield extended - protected - position, and outer bias means for biasing said outer shield toward said extended position, permitting said shield move to said retracted position in response to a proximally directed force applied to body tissue operated surface of said outer shield, said bias means returning said outer shield to said outer shield extended position when the force applied to said outer shield is removed so that said penetrating apex shield and outer shield are movable independently of one another and can be in at least three extreme mutual positions: their simultaneous location in said extended and outer shield extended position, respectively; location of said penetrating apex shield in said extended position, and said outer shield in said outer shield retracted position; location of both in said retracted and outer shield retracted position, respectively.

19. Device according to Claim 18, wherein said outer cutting means have at least one outer cutting member made as a knife mounted on said penetrating end between said penetrating apex shield and said outer shield so that the knife cutting edge protrudes above the surface of said sloping wall.

20. Device according to Claim 18, wherein there are two outer cutting members.

21. Device according to Claim 18, wherein there are three outer cutting members.

22. Device according to Claim 18, wherein said outer shield surrounds said penetrating apex, penetrating apex shield, and outer cutting means.

23. Device according to Claim 22, wherein said outer shield is made tubular, and said outer biasing means is made as a compression spring.

24. Device according to Claims 13, 19, wherein said outer shield is made as two-sided low profile shield, and comprises two rigidly interconnected plate-shaped shield members mounted bilaterally of said outer cutting means.

25. Device according to Claim 1, wherein:

- said portal unit has a portal housing located on the proximal end of said tubular cannula;
- inner seals located in said portal housing and aimed to maintain insufflation of the body cavity;
- locking means which being in lock position locks said protector means into protected position, and being in an unlock position unlocks said protector means so that said locking means unlocks said protector means when said cutting means is located distally of said seals.

26. Device according to Claim 25, wherein said locking means has obturator-situated controlling member, partially protruding laterally of said obturator and adapted for the interaction with inner surface of said tubular cannula for moving abutting member, which is spring-loaded to said obturator and has abutting surface for rigid abutment of said protector means members, when said locking means is in said lock position.

27. Device according to Claims 18, 26, wherein each of said independent shields has independent said locking means.

28. Device according to Claims 24, 27, wherein said penetrating apex shield and said

outer shield have independent said locking means.

29. Device according to Claim 18, 26, wherein there is said locking means for one of said shields, which in said protected position ensures protection of said penetrating apex and of all said cutting means.

30. Device according to Claims 23, 29, wherein there is said locking means to said outer shield.

31. Device according to Claim 16, wherein there are dilating means for dilating said orifice in body cavity wall, formed by said penetrating apex and cutting means to the dimensions permitting entry of said tubular cannula, therewith said dilating means comprises said sloping side wall and sloping edge of said open distal end of said tubular cannula so that said sloping edge of tubular cannula is located in the plane intersecting said device longitudinal central axis at an acute angle, whereas proximal end of said cutting edge of outer cutting means is situated proximally of distal point of said tubular cannula edge.

32. Device according to Claim 1, wherein there is portal unit mounting means for mounting said portal unit in said orifice of body cavity wall which has inner mounting means made as inflated cuff mounted on said tubular cannula, and there is connector means for said cuff connection to the external gas supply.

33. Device according to Claim 32, wherein there is an outer mounting means comprising restraining member movable along said tubular cannula, and resistance means precluding spontaneous proximal displacement of said restraining member.

34. Device according to Claim 33, wherein said restraining member has a flange and an orifice said tubular cannula passes through, and said resisting means is made as engagement means and has restraining member engagement protrusions situated on inner of said orifice, and tubular cannula engagement protrusions situated on outer surface of said tubular cannula.

35. Device according to Claim 32, wherein said connection means comprises connector with rebound valve and a passage connecting said connector and said cuff and passing through the wall of said tubular cannula.

36. Device according to Claim 32, wherein there is outer sealing means to maintain insufflation of the body cavity precluding gas leakage out of body cavity into the atmosphere through the spacing between said portal unit and walls of said orifice in body cavity wall, and said outer sealing means has seal member, and said inflated cuff serves as such.

37. Device according to Claim 36, wherein there is cuff traction means ensuring retaining of said inflated cuff against inner surface of body cavity wall in its inflated state.

38. Device according to Claim 34, 35, 37, wherein said outer mounting means serve as said retaining means.

39. A safety trocar assembly comprising:

- portal unit having elongated obturator with penetrating distal end;
- longitudinal axis of trocar assembly;
- penetrating means for orifice formation in body cavity wall, having at least two penetrating zones: first penetrating zone and second penetrating zone;
- a protector means, having protector member for each of said penetrating zones and adapted to actuate between a retracted and an extended position, when each said protector member has body tissue operated surface which is the section of said protector member surface which contacts with body cavity wall tissue and while interacting with body tissue results in displacement of said protector member opposite of said extended position toward said retracted position so that displacement vectors of said protector members between their said retracted and extended positions are in the planes parallel to said longitudinal axis;
- bias means for each of said protector members for biasing said protector members toward said extended position and for permitting said protector members move to said retracted

position in response to a force applied to said tissue operated surface, said bias means, returning said protector members to said extended position when the force applied to said tissue operated surface is removed so that said protector members move independently of one another between their said extended and retracted positions.

40. Device according to Claim 39, wherein said penetrating means at the level of at least one said penetrating zone is made as cutting member with cutting edge so that said cutting edge is situated in the plane parallel to said longitudinal axis, and this plane is the cutting plane for said cutting edge.

41. Device according to Claim 40, wherein said bias means is made as resilient members.

42. Device according to Claim 41, wherein said protector members are made as separate shields.

43. Device according to Claim 41, wherein said protector members are made as a common shield for at least two penetrating zones, a penetrating means made as said cutting members with common cutting edge so that each of said cutting members is protected by corresponding regions of said common shield so that each of said common shield regions is by its own said bias means.

44. Device according to Claim 41, wherein there is at least one penetrating zone level limited by two planes perpendicular to said longitudinal axis, one of them intersecting the extreme distal point of said penetrating zone, whereas another one intersects the extreme proximal point of said penetrating zone.

45. Device according to Claim 41, wherein there is a blunt penetrating apex, and said first and second penetrating zones are situated proximally of said blunt penetrating apex.

46. Device according to Claim 43, wherein said common shield and said bias means are made as a single resilient part having a slat which in said extended position is basically situated parallel to said cutting edge, and resilient elements, each of them being connected to said slat by one its end, whereas the other one is connected with the members of said penetrating end immovable relative to said cutting edge.

47. Device according to Claim 43, wherein said common shield in said extended position extends beyond the bounds of said cutting edge no more than 2 mm in the direction parallel to said cutting plane of said cutting edge.

48. Device according to Claim 44, wherein there are at least two said penetrating zone levels, one being distal and another one, proximal.

49. Device according to Claim 44, wherein there are at least two said penetrating zones in said penetrating zone level.

50. Device according to Claim 49, 42, 45, wherein there are two said cutting members, whereas said protector members are made as plates situated parallel to the corresponding said cutting members, and said bias means are made as compression springs and said blunt penetrating apex is in line with said longitudinal axis.

51. Device according to Claim 48, wherein a section of said penetrating means at the level of said penetrating zone and corresponding to it said protector member and bias means are a penetration unit so that said distal and proximal penetration units are made so that the penetration into body tissue at the level of said proximal penetration unit occurs under higher tissue tension than the penetration of tissue at the level of said distal penetration unit.

52. Device according to Claim 51, wherein rigidity of said proximal bias means of said proximal protector unit is higher than the rigidity of said distal bias means of said distal protector unit.

53. Device according to Claims 46, 47, 48, wherein there is more than one said common shield, and they are situated around said longitudinal axis at regular intervals from each other.

54. Device according to Claims 52, 53, wherein said distal penetrating unit has said cutting member, said protector member is made plate-shaped and situated parallel to said cutting member, and said bias means is made as a flat compression spring.

55. Device according to Claim 39, wherein there is a portal unit with elongated tubular cannula, having an open distal end through which said penetrating end of said obturator is exposed.

56. Safety trocar assembly for making orifice in body cavity wall and for portal unit mounting in said orifice, comprising:

- central longitudinal axis;
- elongated obturator with distal penetrating end, having blunt apex and cutting means situated proximally of said blunt apex;

57. Device according to Claim 56, wherein said blunt apex has:

- a base constituted by the section of said blunt apex situated at distal point level of said cutting means;
- a blunt apex distal point formed by the extreme distal point on the surface of said blunt apex;
- blunt apex central axis constituted by the axis parallel to said central longitudinal axis and intersecting said blunt apex distal point;
- a diameter of said blunt apex base constituted by the diameter of a circumference made at the level of said base blunt apex and circumscribing the most protruding points on said surface of said base blunt apex so that the center of said circumference is located on said central axis blunt apex, and said circumference is in the plane perpendicular to said central axis blunt apex.

58. Device according to Claim 57, wherein said obturator has a diameter constituted by the diameter of the largest circumference with the centers on said central longitudinal axis made in the planes perpendicular to said central longitudinal axis, and circumscribing the most protruding points on the surface of said obturator at the distal half section of said obturator so that said diameter of base blunt apex constitutes less than 75% of said obturator diameter.

59. Device according to Claim 58, wherein said diameter of base blunt apex preferably constitutes less than 30% of said obturator diameter.

60. Device according to Claim 57, wherein end of said blunt apex is round.

61. Device according to Claim 60, wherein the diameter of said blunt apex end is less than said diameter of base blunt apex.

62. Device according to Claim 57, wherein said blunt apex central axis coincides with said central longitudinal axis.

63. Trocar assembly comprising:

- longitudinal central axis;
- portal unit with elongated tubular cannula, having an open distal end having at least one sloping edge situated in the plane intersecting said longitudinal central axis at an acute angle;
- trocar unit having elongated obturator adapted to be removably inserted through said cannula and having a cutting means for making orifice in body cavity wall, and exposed through said open distal end of said cannula;
- said cutting means has at least one cutting edge so that proximal end of said cutting edge is located proximally of distal point of said sloping edge of said tubular cannula.

64. Device according to Claim 57, wherein there is a cutting plane of said cutting edge

constituted by the plane intersecting said cutting edge and said longitudinal central axis;

65. Device according to Claim 64, wherein said cutting plane is the symmetry plane of said sloping edge.

66. Device according to Claim 63, wherein there are more than one said cutting edge having differing said cutting planes.

67. Device according to Claim 66, wherein the number of said sloping edges corresponds to the number of said cutting planes.

68. Trocar assembly comprising:

- portal unit with elongated tubular cannula and portal unit mounting means for mounting said portal unit in orifice of body cavity wall which has inner mounting means made as inflated cuff mounted on said tubular cannula, and there is connector means for said cuff connection to the external gas supply.

69. Device according to Claim 68, wherein there is an outer mounting means comprising restraining member movable along said tubular cannula, and resistance means precluding spontaneous proximal displacement of said restraining member.

70. Device according to Claim 69, wherein said restraining member has a flange and an orifice said tubular cannula passes through, and said resisting means is made as engagement means and has restraining member engagement protrusions situated on inner of said orifice, and tubular cannula engagement protrusions situated on outer surface of said tubular cannula.

71. Device according to Claim 68, wherein said connection means comprises connector with rebound valve and a passage connecting said connector and said cuff and passing through the wall of said tubular cannula.

72. Device according to Claim 68, wherein there is outer sealing means to maintain insufflation of the body cavity precluding gas leakage out of body cavity into the atmosphere through the spacing between said portal unit and walls of said orifice in body cavity wall, and said outer sealing means has seal member, and said inflated cuff serves as such.

73. Device according to Claim 72, wherein there is cuff traction means ensuring retaining of said inflated cuff against inner surface of body cavity wall in its inflated state.

74. Device according to Claim 70, 71, 73, wherein said outer mounting means serve as said cuff traction means.

75. A safety trocar assembly comprising:

- portal unit with elongated, tubular cannula having an open distal end;
- said portal unit has a portal housing located on the proximal end of said tubular cannula;
- trocar unit having elongated obturator adapted to be removably inserted through said cannula and having a penetrating end exposed through said open distal end of said cannula, and a cutting means for making orifice in body cavity wall, situated on said penetrating end;
- a protector means situated on said obturator and adapted to actuate between a retracted and an extended protected position;
- bias means for biasing said protector means toward said extended position and for permitting said protector means move to said retracted position in response to a proximally directed force applied to said protector means, returning said shield to said extended position when the force applied to said protector means is removed;
- inner seals located in said portal housing and aimed to maintain insufflation of the body cavity;
- locking means, which being in lock position, locks said protector means into protected position, and being in an unlock position unlocks said protector means so that said locking means unlocks said protector means when said cutting means is located distally of said seals.

76. Device according to Claim 75, wherein said locking means has obturator-situated controlling member, partially protruding laterally of said obturator and adapted for the interaction with inner surface of said tubular cannula for moving abutting member, which is spring-loaded to said obturator and has abutting surface for rigid abutment of said protector means members, when said locking means is in said lock position.

77. Device according to Claim 76, wherein said cutting means is made as knives, said protector means is made as a tubular member, and said bias means is made as a spring.

78. Safety trocar assembly comprising trocar unit having:

- elongated obturator;
- penetrating means situated on distal end of said obturator and having at least one penetrating zone;
- a protector means situated on said obturator and comprising shield for said penetrating zone and adapted to actuate between a retracted and an extended position;
- bias means for biasing said shield toward said extended position, and for permitting said shield move to said retracted position;
- longitudinal central axis of said obturator;
- displacement vector of said shield between their said extended and retracted positions is in the plane parallel to said longitudinal axis;
- said shield is made as one-sided low profile shield, and situated on one side of cutting plane of said penetrating zone, and along the proximal screen area has the shield local comparative height less than 0.8.

79. Device according to Claim 78, wherein there is a portal unit with elongated tubular cannula, having an open distal end through which said penetrating means and said shield are exposed so that said shield has shield open part and as such serves the section of said shield which by said shield location in said retracted position is situated between two planes perpendicular to said longitudinal central axis so that one of them intersects the distal point of

said shield, and the other said plane intersects the proximal point of the section of inner surface of said shield protruding beyond the bounds of the members of said trocar assembly immovable with regard to said penetrating means and located distally of said open distal end of tubular cannula.

80. Device according to Claim 79, wherein said shield open part situated proximally of said screen area has the shield local comparative height less than 0.8.

81. Device according to Claim 79, wherein inner diameter of said tubular cannula at the level of said open distal end is within 10 mm to 12.5 mm range so that said maximal height of said shield along the entire said shield open part is less than 3.5 mm.

82. Device according to Claim 79, wherein inner diameter of said tubular cannula at the level of said open distal end is within 5 mm to 6.5 mm range so that said maximal height of said shield along the entire said shield open part is less than 2 mm.

83. Device according to Claim 78, wherein said penetrating zone has cutting edge situated in the plane parallel to said longitudinal central axis, and said cutting edge has inner end point and outer end point so that said inner end point is situated closer to said longitudinal central axis than said outer end point.

84. Device according to Claim 83, wherein said shield is direct shield, and by displacement from said extended position to said retracted one, it gradually exposes said cutting edge from said inner end point to said outer end point.

85. Device according to Claim 83, wherein said shield is delineating shield in which tissue operated edge is made approximately congruent to said cutting edge and exposes said cutting edge approximately concurrently along the entire length.

86. Device according to Claim 83, wherein said shield is inverted shield and by its

displacement from said extended to said retracted position it gradually exposes said cutting edge from said outer end point to said inner end point.

87. Device according to Claim 83, wherein there is more than one said penetrating zone and there is an inverted multishield, having protector members for each said penetrating zone so that said protector members are on a common base and upon displacement from extended to retracted position expose said penetrating zones from proximal to distal one.

88. Device according to Claim 80, 84, wherein said penetrating means is made as a knife, where said cutting edge is made in the same plane with longitudinal central axis, said shield is made plate-shaped, and bias means is made as a flat compression means.

89. Device according to Claim 80, 86, wherein there is a blunt apex, two said cutting edges situated on the common base set in a longitudinal groove of said distal end of said obturator so that said cutting edges are situated from two opposite sides of said obturator distal end at an acute angle to said longitudinal central axis, whereas said shield is made plate- shaped and has two said tissue operated edges, one for each said cutting edge so that said tissue operated edges are made tilted with regard to said longitudinal axis so that their tilt angle is less than said tilt angle of cutting edges, and said bias means is made as a compression spring, and there is a lock means for blocking said shield in said extended position.

90. Device according to Claim 89, 80, wherein said cutting edge is situated at an acute angle to said longitudinal central axis, and said tissue operated edge of said shield is made stepwise, and bias means is made as a compression spring,

91. A safety trocar assembly comprising:

- longitudinal central axis;
- portal unit with elongated, tubular cannula having an open distal end;
- trocar unit having elongated obturator adapted to be removably inserted through said cannula and having a penetrating end exposed through said cannula open distal end;

- penetrating means situated on said penetrating end;

- a protector means for said penetrating means having at least one shield situated on said obturator and adapted to actuate between a retracted and an extended position when said shield protects said penetrating means;

- shield open part, this being the part of said shield which when said protector means is in said retracted position, is situated distally of the plane perpendicular to said longitudinal central axis and intersecting the proximal point of the section of outer surface of said shield protruding beyond the bounds of the members of said trocar assembly immovable with regard to said penetrating means and located distally of said cannula open distal end;

- common projection of outer surfaces of the members of said trocar assembly situated distally of said cannula open distal end onto the plane perpendicular to said longitudinal central axis, having the center in the intersect point of said plane and said longitudinal central axis;

- projection width of said shield and as such serves the distance between said common projection center and its most remote point on said shield projection outline;

- relative projection area of said shield outer outline which is the ratio of said projection area of shield outer outline to the area of the circle with radius equal to said projection width of said shield so that said relative projection area of said shield outer outline is always less than 0.4.

92. Device according to Claim 91, wherein said relative projection area of shield outer outline is less than 0.2.

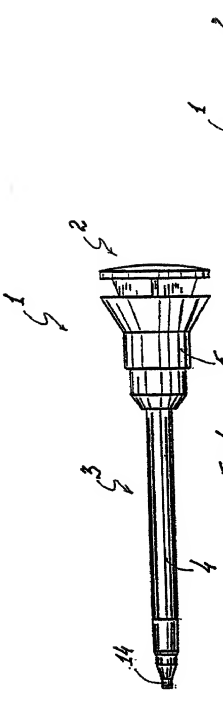
93. A safety trocar assembly comprising:

- trocar unit with penetrating means having at least two penetrating zones - distal and proximal - so that penetration of body tissue at the level of said proximal penetration zone occurs under higher tissue tension than penetration of tissue at the level of said distal penetration zone.

- 94. Device according to Claim 93, wherein said penetrating means at the level
- of said distal and proximal zones are made as cutting members so that said distal

cutting member is made sharper than said proximal cutting member.

95. Device according to Claim 93, wherein there is a protector member for each of said penetrating zones so that the displacement of said proximal protector member from the extended to the retracted position demands greater effort that the displacement of said distal protector member.



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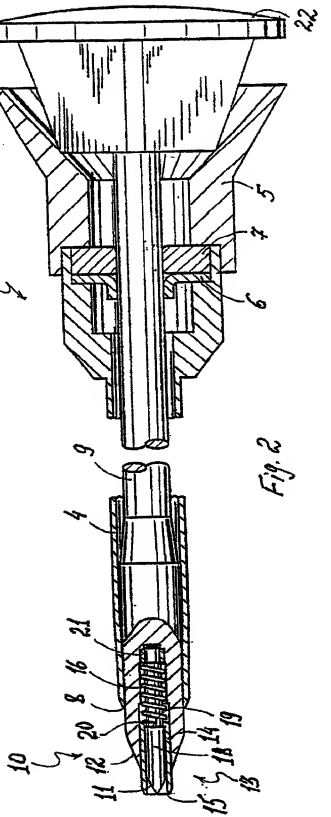

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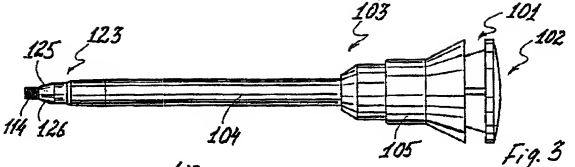

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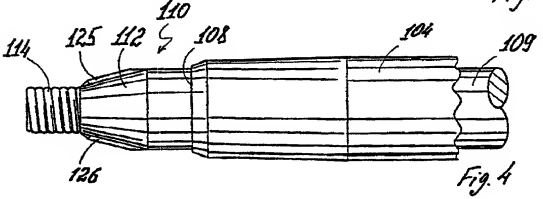

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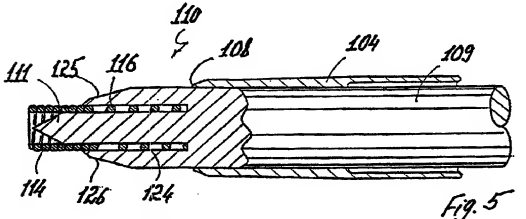

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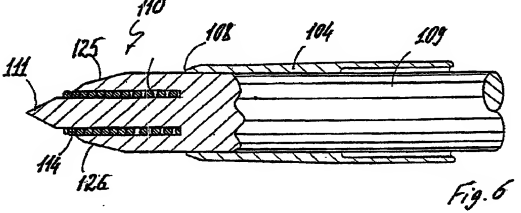

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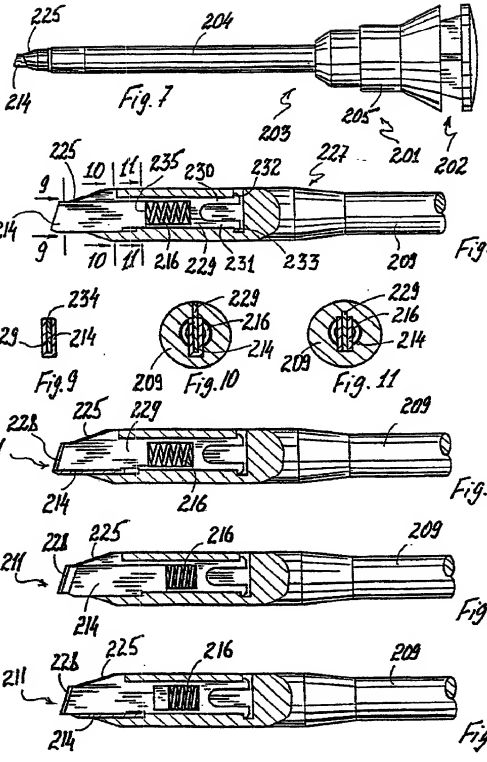
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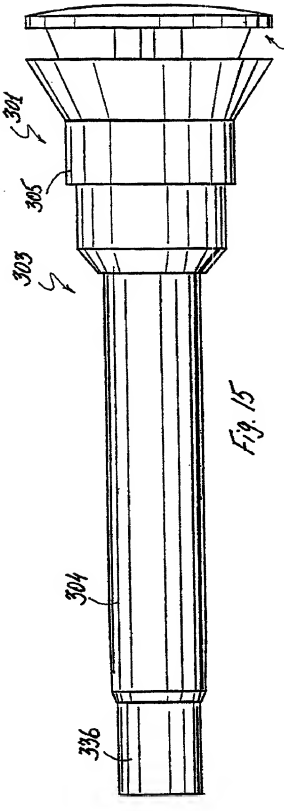
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Fig. 15

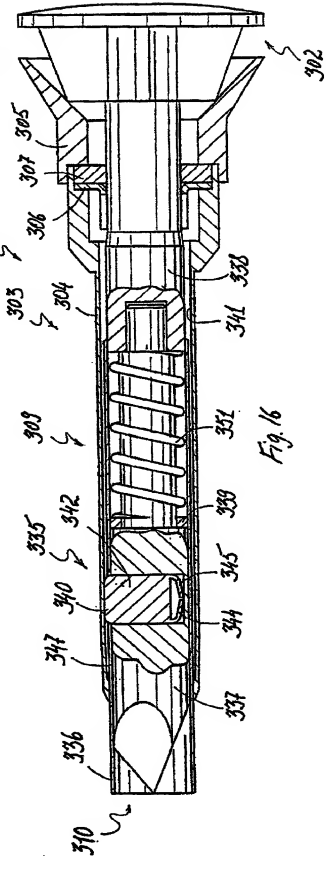
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Fig. 16

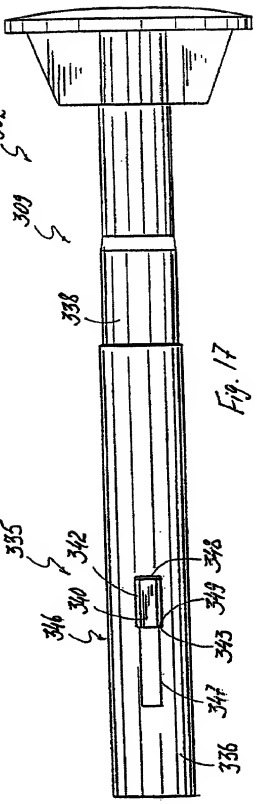
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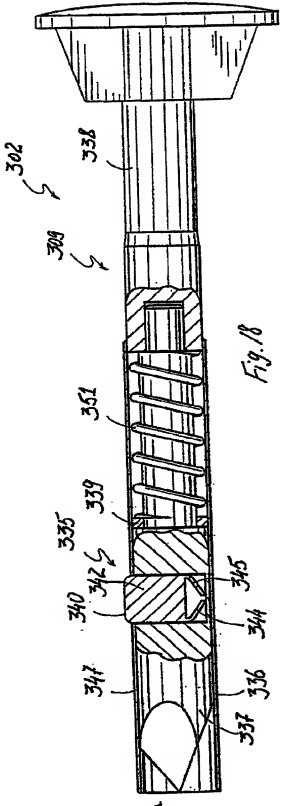
Fig. 17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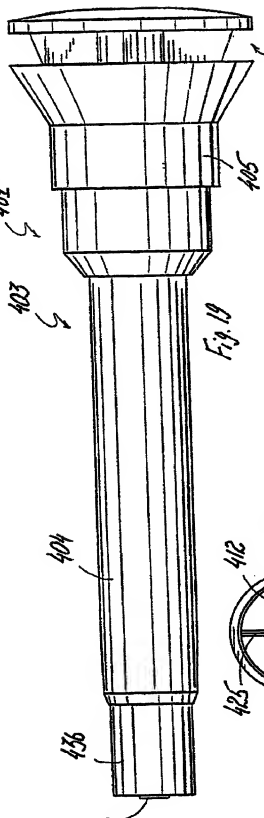

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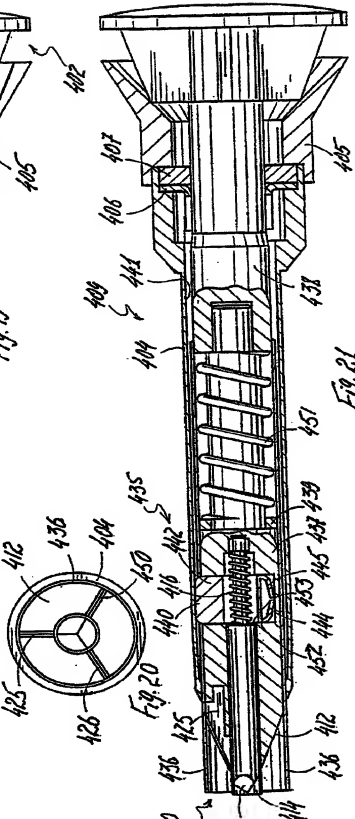

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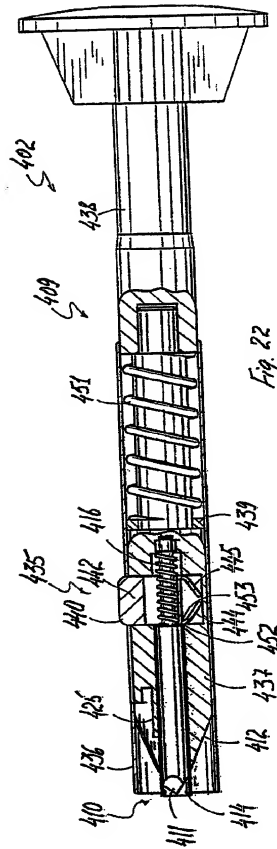
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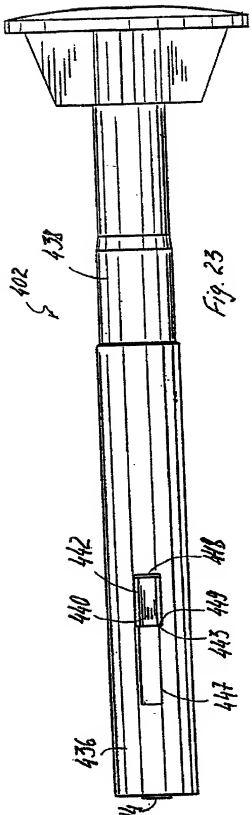
Fig. 22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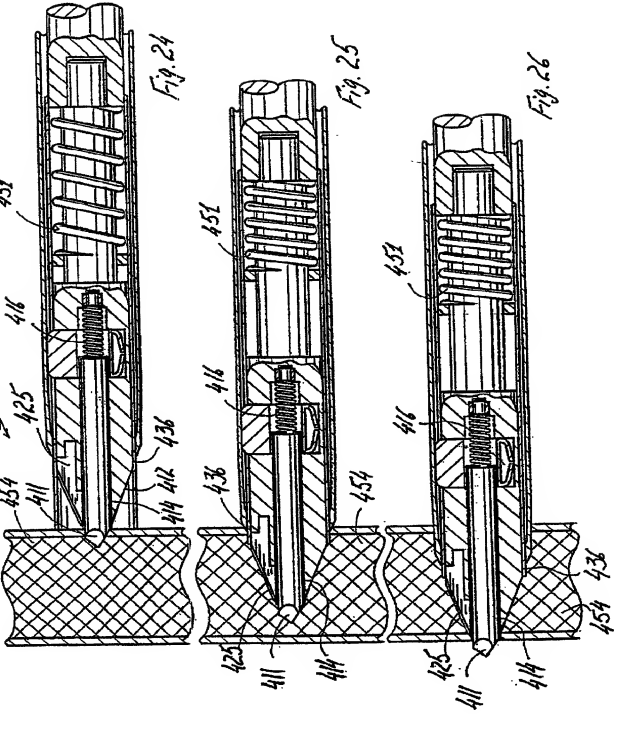

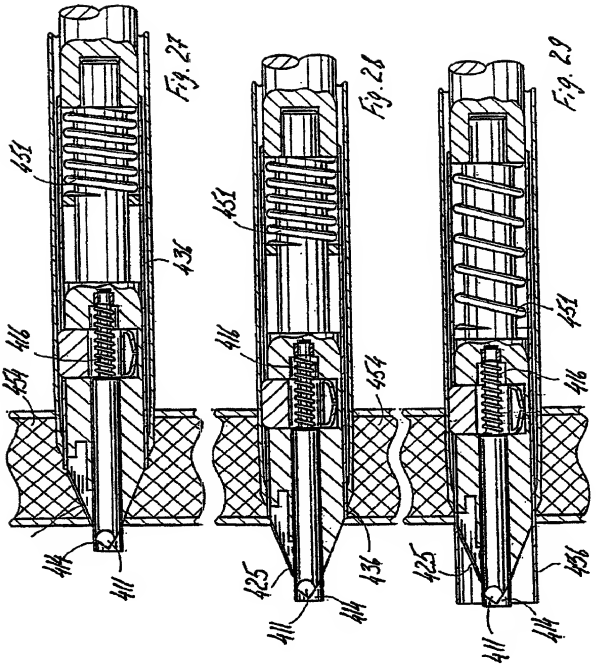
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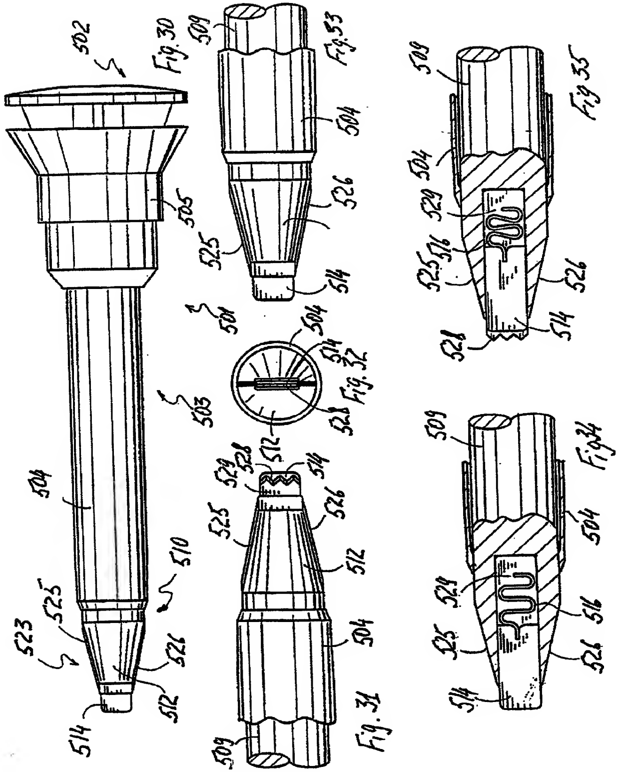

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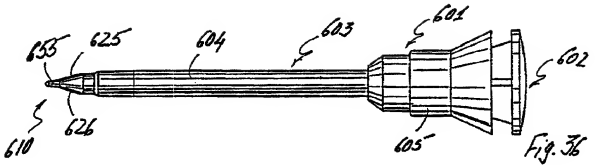

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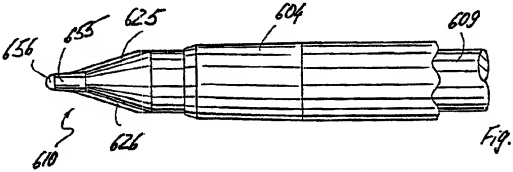

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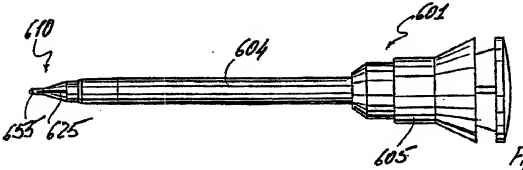

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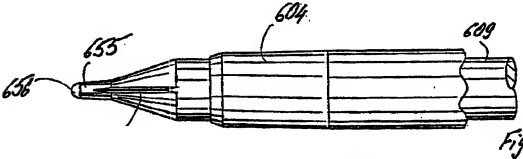

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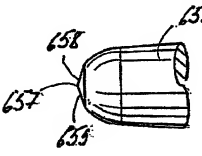

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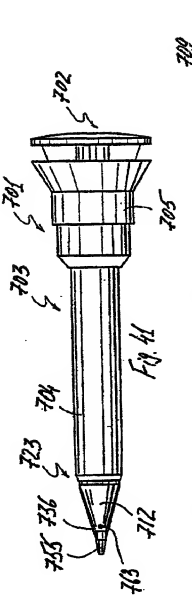

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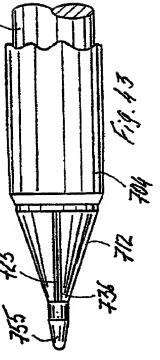

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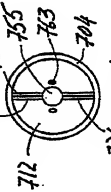

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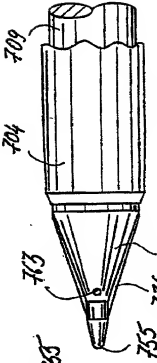

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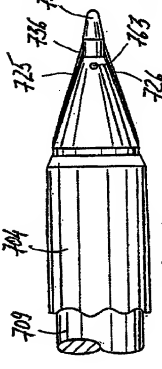

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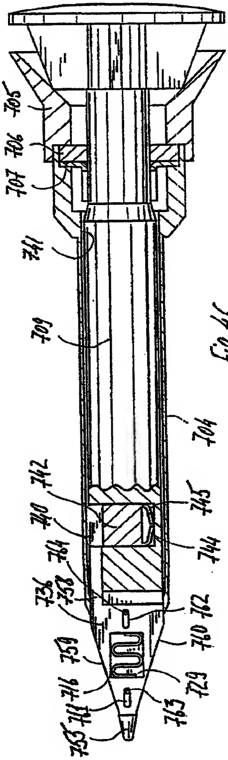
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Fig. 46

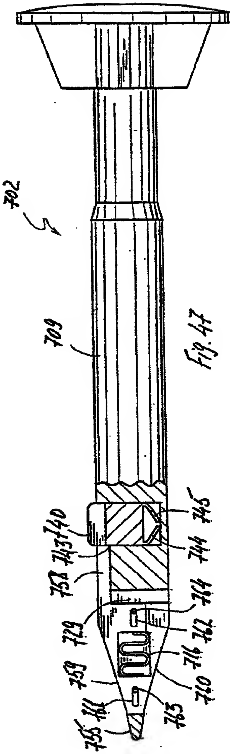
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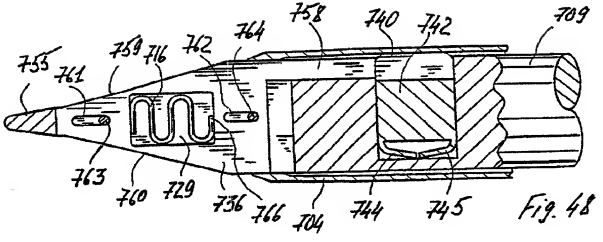
Fig. 47



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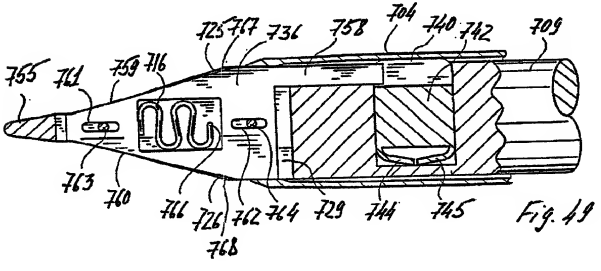

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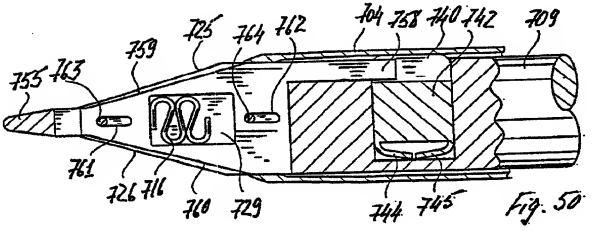

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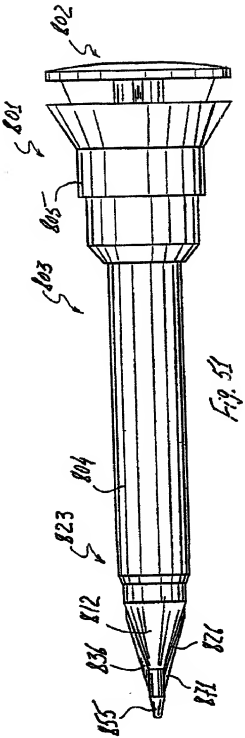

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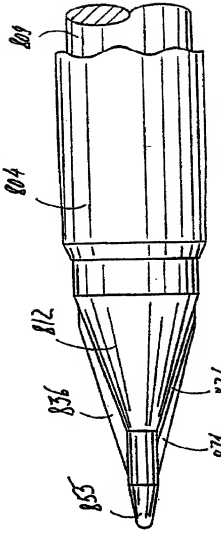

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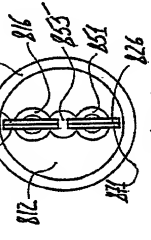

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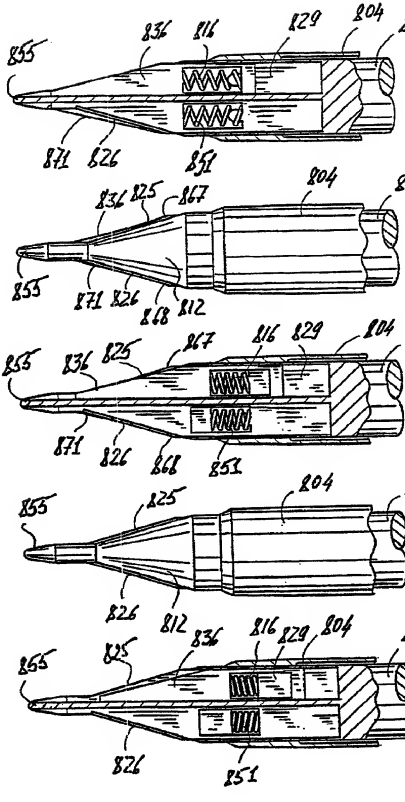
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Fig. 57
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Fig. 58

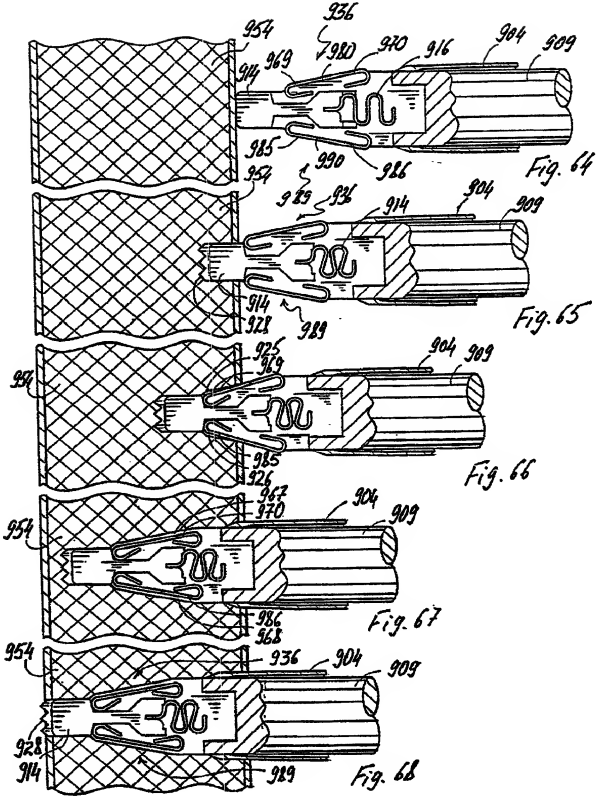


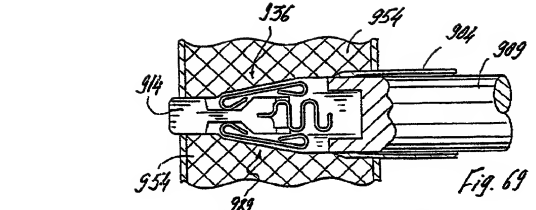
Fig. 64

Fig. 65

Fig. 66

Fig. 67

Fig. 68



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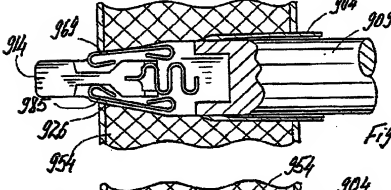

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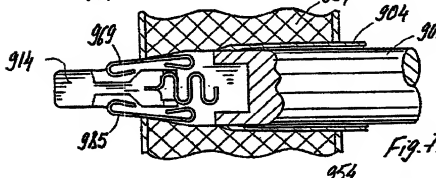

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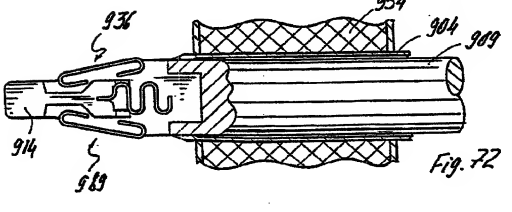

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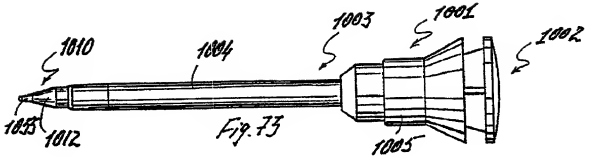

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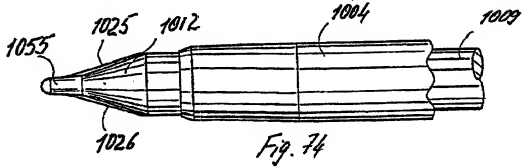


Fig. 74

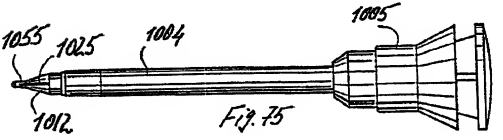
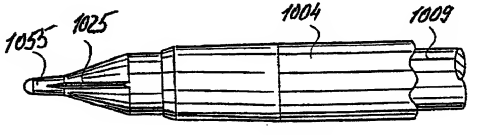


Fig. 75



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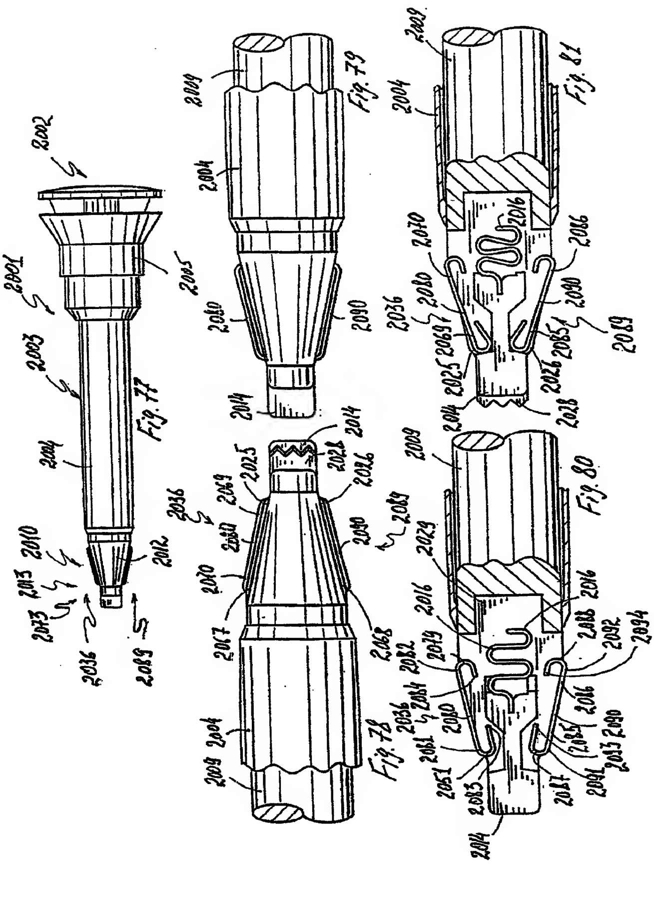


Fig. 77
Fig. 78
Fig. 79
Fig. 80
Fig. 81

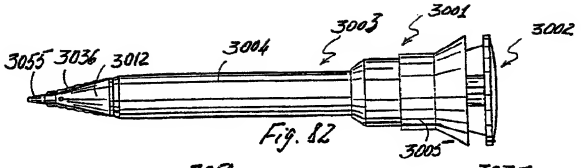


Fig. 82

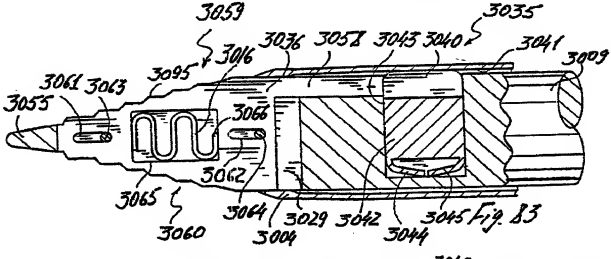


Fig. 83

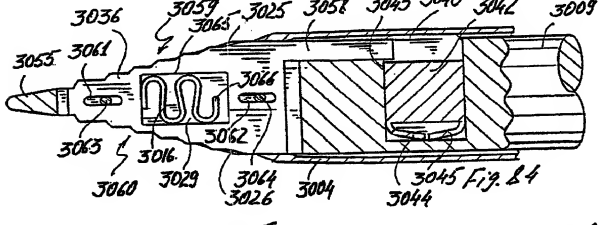


Fig. 84

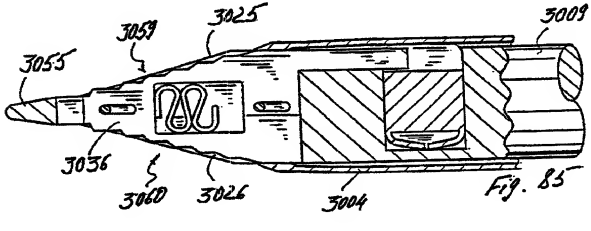


Fig. 85

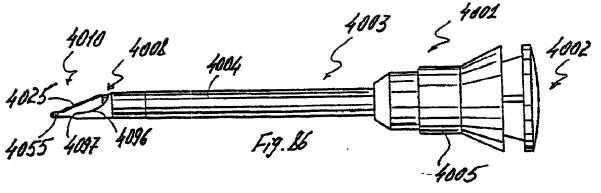
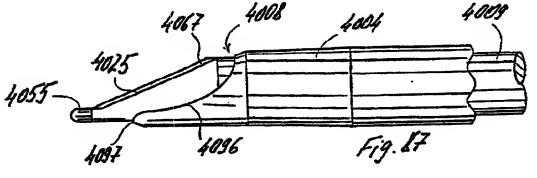


Fig. 86



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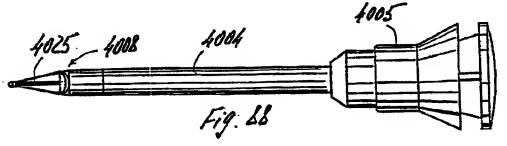

Fig. 88

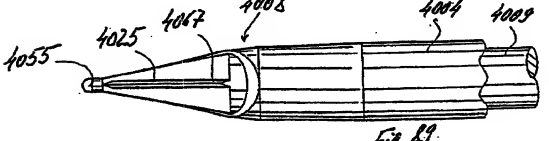

Fig. 89

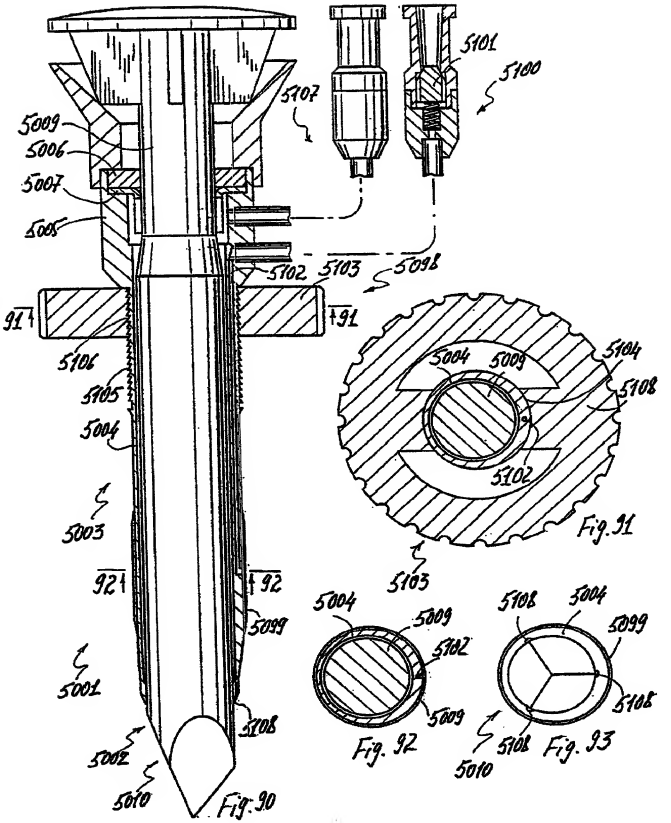
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Fig. 90
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Fig. 91
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Fig. 93

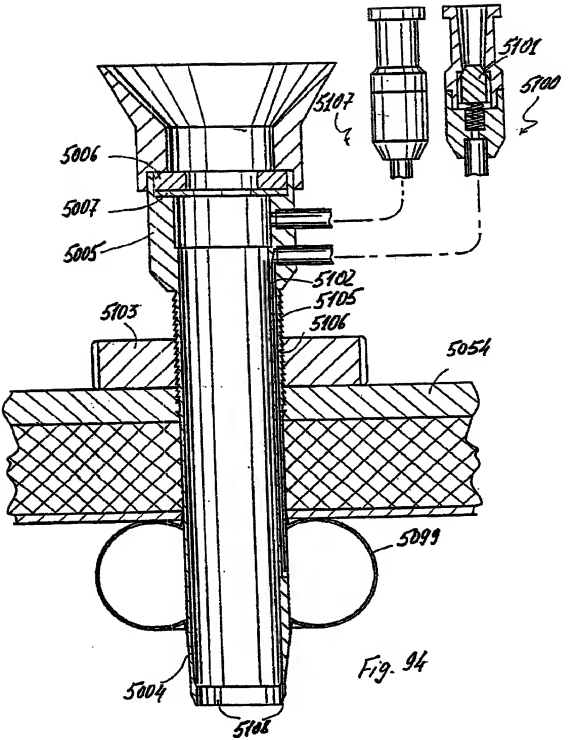
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Fig. 94

PTO/SB/01 (03-01)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

[X] Declaration Submitted with Initial Filing OR [ ] Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	
First Named Inventor	Sergey Popov
COMPLETE IF KNOWN	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	Michael J. Hayes

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SAFETY TROCAR ASSEMBLY

(Title of the Invention)

the specification of which

[ ] is attached hereto

OR

[X] was filed on (MM/DD/YYYY) 03/14/2000 as United States Application Number or PCT International

Application Number PCT/IB00/00406 and was amended on (MM/DD/YYYY) 05/15/2001 (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	Certified Copy Attached? NO
IL-128989	Israel	03/15/1999	[ ]	[ ]	[X]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]
			[ ]	[ ]	[ ]

[ ] Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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DECLARATION Utility or Design Patent Application

Direct all correspondence to: [x] Customer Number or Bar Code Label [ ] OR [x] Correspondence address below

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: [ ] A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]): Sergey
Family Name or Surname: Popov

Inventor's Signature: [signature] Date: 09/13/01

Residence: City: Be'er Sheva State: Israel Country: Israel Citizenship

Mailing Address: P.O. Box 4583

City: Be'er Sheva State: Israel ZIP: 84144 Country: Israel

NAME OF SECOND INVENTOR: [ ] A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]):
Family Name or Surname:

Inventor's Signature: Date:

Residence: City: State: Country: Citizenship:

Mailing Address:

City: State: ZIP: Country:

[ ] Additional inventors are being named on the ____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.